ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Voydeya 50 mg film-coated tablets
Voydeya 100 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Voydeya 50 mg film-coated tablets

Each film-coated tablet contains 50 mg of danicopan.

Voydeya 100 mg film-coated tablets

Each film-coated tablet contains 100 mg of danicopan.

Excipient with known effect

Each 50 mg tablet contains 57.5 mg of lactose in form of lactose monohydrate.
Each 100 mg tablet contains 115 mg of lactose in form of lactose monohydrate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Voydeya 50 mg film-coated tablets

White to off-white, round film-coated tablets, “DCN” above “50” debossed on one side, plain on the other side. Each tablet is approximately 8 mm.

Voydeya 100 mg film-coated tablets

White to off-white, round film-coated tablets, “DCN” above “100” debossed on one side, plain on the other side. Each tablet is approximately 10.3 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Voydeya is indicated as an add-on to ravulizumab or eculizumab for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have residual haemolytic anaemia (see section 5.1).

4.2 Posology and method of administration

Treatment should be initiated by a healthcare professional experienced in the management of patients with haematological disorders.

Posology

The recommended starting dose is 150 mg three times a day administered orally, approximately 8 hours apart (± 2 hours). Dose can be increased to 200 mg three times a day after a minimum of 4 weeks of treatment depending on clinical response.

Missed doses
If a dose is missed, patients should be advised to take it as soon as it is remembered unless it is almost time for the next dose in which case patients should skip the missed dose and take the medicinal product at the next regularly scheduled time. Patients should be advised not to take 2 doses or more at the same time.

Discontinuation
Due to the possibility of alanine aminotransferase (ALT) elevations after treatment cessation (see section 4.4), if treatment is discontinued, the dose should be tapered over a 6-day period until complete cessation, as follows:
- 100 mg regimen: 100 mg twice a day for 3 days, followed by 100 mg once a day for 3 days.
- 150 mg regimen: 100 mg three times a day for 3 days, followed by 50 mg three times a day for 3 days.
- 200 mg regimen: 100 mg three times a day for 3 days, followed by 100 mg twice a day for 3 days.

Special populations

Elderly
No dose adjustment is required in elderly patients. However, experience with danicopan in patients ≥ 65 years of age is limited (see section 5.1).

Renal impairment
No dose adjustment is required in patients with mild (estimated glomerular filtration rate [eGFR] ≥ 60 to < 90 mL/min/1.73 m^2) or moderate (eGFR ≥ 30 to < 60 mL/min/1.73 m^2) renal impairment. In patients with severe renal impairment (eGFR < 30 mL/min/1.73 m^2), the recommended starting dose is 100 mg three times a day administered orally, approximately 8 hours apart (± 2 hours). Dose can be increased to 150 mg three times a day after a minimum of 4 weeks of treatment depending on clinical response (see sections 4.4 and 5.2).

Hepatic impairment
No dose adjustment is required in patients with mild (Child-Pugh Class A) to moderate (Child-Pugh Class B) hepatic impairment (see section 5.2). Studies have not been conducted in patients with severe (Child-Pugh Class C) hepatic impairment. Therefore, danicopan is not recommended in this patient population (see section 4.4).

Paediatric population

The safety and efficacy of Voydeya in children aged less than 18 years have not yet been established. No data are available.

Method of administration

Oral use.
Tablets should be taken with food (meal or snack) (see section 5.2).

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Patients with unresolved *Neisseria meningitidis* infection at treatment initiation (see section 4.4).

- Patients who are not currently vaccinated against *Neisseria meningitidis* unless they receive prophylactic treatment with appropriate antibiotics until 2 weeks after vaccination (see section 4.4).

4.4 Special warnings and precautions for use

General

Danicopan must not be administered as monotherapy as the efficacy has not been established. It should only be prescribed as an add-on to ravulizumab or eculizumab.

Serious infections

Meningococcal infections
Patients receiving complement inhibitor therapy may have increased susceptibility to meningococcal infections (*Neisseria meningitidis*). Patients must be up to date on their meningococcal vaccines according to current national guidelines for vaccination use, prior to receiving the first dose of danicopan.

Patients who initiate treatment less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Patients must be vaccinated against serogroups A, C, Y, and W135 to prevent the commonly pathogenic meningococcal serogroups. Vaccination against serogroup B, where available, is also recommended. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

All patients treated with danicopan should be monitored for early signs of meningococcal infection and sepsis, evaluated immediately if infection is suspected, and treated with appropriate antibiotics. Patients should be informed of these signs and symptoms and steps should be taken to seek medical care immediately.

Other serious infections
Danicopan should be administered with caution to patients with active systemic infections. Danicopan selectively blocks the activation of the complement alternative pathway; therefore, patients may have increased susceptibility to serious infections (other than *Neisseria meningitidis*). Prior to initiating danicopan as add-on to ravulizumab or eculizumab, it is recommended that patients initiate immunisation according to current immunisation guidelines.

Severe renal impairment

Patients with severe renal impairment that dose escalate to 150 mg three times a day should be monitored for adverse events during treatment with danicopan due to higher exposure expected in these patients.

Low body weight

Patients weighing < 60 kg should be monitored for adverse events during treatment with danicopan due to higher exposure expected in these patients.

Hepatic enzymes increase

Alanine aminotransferase (ALT) elevations have been observed in clinical trials (see section 4.8). It is recommended that liver enzyme tests are performed before treatment begins. Following initiation of treatment, routine chemistry laboratory monitoring as per PNH management is recommended. Treatment interruption or discontinuation should be considered if elevations are clinically significant or if patients become symptomatic. Danicopan is not recommended in patients with severe hepatic impairment (see section 4.2).

Discontinuation

At doses higher than 200 mg three times a day, ALT elevations occurred after treatment cessation without dose tapering in healthy subjects (see section 4.9). Upon discontinuation, the dose should be tapered over 6 days (see section 4.2).

Excipients with known effect

Lactose
This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Effects of danicopan on other medicinal products

P-gp substrates
Co-administration of a single oral dose of 180 mg fexofenadine, a P-gp substrate, with 150 mg three times daily doses of danicopan resulted in increased fexofenadine C_{max} and $AUC_{0\text{-}inf}$ by 1.42-fold and 1.62-fold, respectively. The results suggest that danicopan is a mild inhibitor of P-gp. Caution may be needed in co-administering medicinal products that are known to be substrates of P-gp (such as dabigatran, digoxin, edoxaban, fexofenadine, tacrolimus).

BCRP substrates
Co-administration of a single oral dose of 20 mg rosuvastatin, a BCRP substrate, with 200 mg three times daily doses of danicopan resulted in increased rosuvastatin C_{max} and $AUC_{0\text{-}inf}$ by 3.29-fold and 2.25-fold, respectively. This result suggests that danicopan is an inhibitor of BCRP. Caution may be needed in co-administering medicinal products that are known to be substrates of BCRP (such as rosuvastatin and sulfasalazine).

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of danicopan in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity at therapeutically relevant dose (see section 5.3). As a precautionary measure, it is preferable to avoid the use of Voydeya during pregnancy.

Breast-feeding

Available pharmacodynamic/toxicological data in animals have shown excretion of danicopan/metabolites in milk (see section 5.3). A risk to the newborns/infants cannot be excluded. Voydeya should not be used during breast-feeding and breast-feeding should not be initiated until 3 days after treatment discontinuation.

Fertility

No human data on the effect of danicopan on fertility are available. Animal studies have shown potential effects on male fertility and reproductive performance (see section 5.3).

4.7 Effects on ability to drive and use machines

Voydeya has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most common adverse reactions are pyrexia (28.1%), headache (25.0%) and hepatic enzyme increased (11.5%).

Tabulated list of adverse reactions

Table 1 includes adverse reactions reported in clinical trials with danicopan. Adverse reactions are listed by system organ class and preferred term using MedDRA frequency convention very common (≥ 1/10), common (≥ 1/100 to < 1/10), and uncommon (≥ 1/1 000 to < 1/100). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 1: Tabulated list of adverse reactions

MedDRA system order Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)
Nervous system disorders	Headache	
Vascular disorders		Hypertension
Gastrointestinal disorders		Vomiting
Hepatobiliary disorders	Hepatic enzyme increased[a]	
Musculoskeletal and connective tissue disorders		Pain in extremity
General disorders and administration site conditions	Pyrexia	

[a] Hepatic enzyme increased includes preferred terms alanine aminotransferase increased, hepatic function abnormal, hepatic enzyme increased, and transaminases increased.

Description of selected adverse reactions

Hepatic enzyme increase
During the 12-week randomised controlled period of study ALXN2040-PNH-301 laboratory abnormalities related to elevations in ALT levels were observed in 14.0% of patients on danicopan. In danicopan-treated patients, ALT elevations > 3 × the upper limit of normal (ULN) and ≤ 5 × ULN occurred in 8.8% of patients, and > 5 × ULN and ≤ 10 × ULN in 5.3% of patients. All patients were asymptomatic, and all elevations were transient. Some elevations occurred in the context of haemolysis..

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Single doses up to 1 200 mg and multiple doses up to 800 mg twice a day have been taken in healthy volunteers. ALT elevations occurred after treatment cessation without a taper in 2 subjects who

received 500 mg and 800 mg twice a day for 14 days. All abnormal ALT findings were transient, with no evidence of hepatic function abnormality and resolved spontaneously.

In case of overdose, elevations in aminotransferase and other liver parameters may occur. General supportive measures are recommended. It is not known whether danicopan can be removed by dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Immunosuppressants, Complement inhibitors, ATC code: L04AJ09

Mechanism of action

Danicopan binds reversibly to complement factor D (FD) and acts as a selective inhibitor of FD function. By inhibiting FD, danicopan selectively blocks the activation of complement alternative pathway (AP), leading to prevention of the production of multiple effectors, that include C3 fragments, after AP activation. The 2 other complement pathways (classical and lectin) remain active. Danicopan's inhibitory effect on AP activation inhibits the deposition of C3 fragments on PNH red blood cells; such deposition is a key cause of the EVH which can become clinically significant in a small subset of patients with PNH on a C5 inhibitor. Maintenance of C5 inhibition controls the life-threatening pathophysiological consequences of terminal complement activation underlying PNH.

Pharmacodynamic effects

In a clinical trial in patients with PNH with clinically significant EVH treated with ravulizumab or eculizumab, danicopan demonstrated the expected inhibition of AP activity, reduction of plasma Bb (a cleaved product of complement factor B by FD) level, as well as decreased C3 fragment deposition on circulating PNH red blood cells.

Cardiac electrophysiology
Single oral doses of danicopan administered at 400 mg, 800 mg, or 1 200 mg did not prolong QTc interval. There were no categorical alerts of concern regarding electrocardiogram intervals or wave form abnormalities.

Clinical efficacy and safety

The efficacy and safety of danicopan in adult patients with PNH who have clinically significant EVH were assessed in a multiple-region, randomised, double-blind, placebo-controlled, phase 3 study (ALXN2040-PNH-301). The study enrolled 86 patients with PNH who had been treated with a stable dose of ravulizumab or eculizumab for at least the previous 6 months and had anaemia (haemoglobin [Hgb] ≤ 9.5 g/dL [5.9 mmol/L]) with absolute reticulocyte count ≥ 120×10^9/L, with or without transfusion support.

Danicopan was administered in accordance with the recommended dosing described in section 4.2 (150 mg three times a day, and up to a maximum of 200 mg three times a day depending on the clinical response).

Patients were evaluated for history of vaccination and had to be vaccinated against meningococcal infection prior to or at the time of initiating treatment with danicopan if vaccination status within 3 years could not verified.

Patients were randomised to danicopan or placebo three times a day in a 2:1 ratio for 12 weeks in addition to background ravulizumab or eculizumab treatment in both groups. After week 12, all patients received danicopan as an add-on to their background ravulizumab or eculizumab treatment up

to week 24. At the end of the treatment periods (week 24), patients were offered to enter a long-term extension (LTE) period and continued to receive danicopan with background ravulizumab or eculizumab.

Demographic or baseline characteristics were generally balanced between treatment groups. PNH medical history was similar between the treatment group and the placebo control group. The mean age at baseline was 52.8 years and the majority of patients were female (62.8%). Mean haemoglobin levels at baseline were 7.75 g/dL [4.81 mmol/L] and mean reticulocyte counts were 239.40×10^9/L. Within 24 weeks prior to the first dose, 76 patients (88.4%) had pRBC/whole blood transfusions and the mean number of transfusion instances was 2.6. Mean LDH levels were 298.13 U/L and mean FACIT-Fatigue scores were 33.24. The study enrolled 51 patients (59.3%) on ravulizumab and 35 patients (40.7%) on eculizumab.

The primary endpoint was the change in Hgb level from baseline to week 12. Secondary endpoints were the proportion of patients with Hgb increase of ≥ 2 g/dL [1.2 mmol/L] at week 12 in the absence of transfusions, the proportion of patients with transfusion avoidance through week 12, the change from baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue scores at week 12, and change from baseline in absolute reticulocyte count at week 12. Transfusion avoidance was considered as achieved only by the patients who did not receive a transfusion and did not meet the protocol specified guidelines for transfusion from baseline through 12-week treatment period 1.

The primary evidence for efficacy analysis is based on a pre-specified analysis performed when the first 63 randomised participants reached the end (either completed or discontinued) of the 12-week treatment period 1.

Danicopan as an add-on to ravulizumab or eculizumab was superior to placebo as an add-on to ravulizumab or eculizumab for the primary endpoint and resulted in a statistically significant increase in Hgb from baseline to week 12. The LS mean change in Hgb from baseline was 2.94 g/dL [1.82 mmol/L] in the danicopan group compared with 0.50 g/dL [0.31 mmol/L] in the placebo group. The treatment group difference was 2.44 g/dL [1.51 mmol/L] (95% CI: 1.69 [1.05], 3.20 [1.99]); $p < 0.0001$). Danicopan also achieved statistically significant improvement compared to placebo for all 4 secondary endpoints: proportion of patients with Hgb increase of ≥ 2 g/dL [1.2 mmol/L] in the absence of transfusion (59.5% vs. 0%, treatment difference: 46.9 [95% CI: 29.2, 64.7]; $p < 0.0001$), proportion of patients with transfusion avoidance (83.3% vs. 38.1%, treatment difference: 41.7 [95% CI: 22.7, 60.8]; $p = 0.0004$), change in FACIT-Fatigue score (7.97 vs. 1.85, treatment difference: 6.12 [95% CI: 2.33, 9.91]; $p = 0.0021$) and change in absolute reticulocyte count (-83.8 vs. 3.5, treatment difference: -87.2 [95% CI: -117.7, -56.7]; $p < 0.0001$).

Supplemental results at week 12 based on all randomised patients (N = 86) are consistent with those from the primary efficacy analysis (N = 63). Danicopan as an add-on to ravulizumab or eculizumab was superior to placebo as an add-on to ravulizumab or eculizumab for the primary endpoint and resulted in a statistically significant increase in Hgb from baseline to week 12 (see Table 2 and Figure 1). Danicopan also achieved statistically significant improvement compared to placebo for all 4 secondary endpoints (see Table 2).

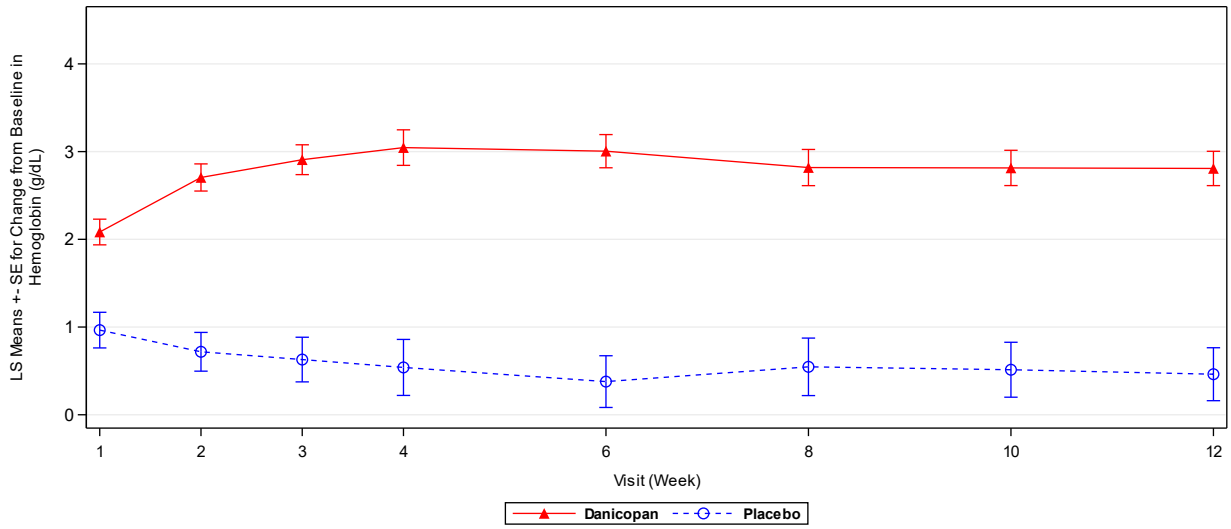
During the 12-week treatment period 1, 14 of 57 (24.6%) patients in the danicopan add-on group were dose escalated from 150 mg to 200 mg three times a day. Four patients (2 randomised to danicopan and 2 randomised to placebo) discontinued treatment during treatment period 1. There were no discontinuations due to haemolysis.

Table 2: Analysis of primary and secondary endpoints at week 12 (all randomised patients)

	Danicopan (add-on with ravulizumab or eculizumab) N = 57	Placebo (add-on with ravulizumab or eculizumab) N = 29
Change in haemoglobin level (primary endpoint)		
Mean change from baseline to week 12 (g/dL [mmol/L])	2.81 [1.74]	0.46 [0.29]
Treatment difference* (95% CI)	2.35 [1.46] (1.63 [1.01], 3.06 [1.90])	
Proportion of patients with haemoglobin increase of ≥ 2 g/dL [1.2 mmol/L] in the absence of transfusion		
At week 12 (%)	54.4	0
Treatment difference** (95% CI)	47.5 (32.6, 62.4)	
Proportion of patients with transfusion avoidance		
Through 12-week treatment period (%)	78.9	27.6
Treatment difference** (95% CI)	48.4 (31.8, 64.9)	
Change in FACIT-Fatigue score		
Mean change from baseline to week 12	8.10	2.38
Treatment difference* (95% CI)	5.72 (2.62, 8.83)	
Change in absolute reticulocyte count		
Mean change from baseline to week 12 (10^9/L)	-92.5	-0.8
Treatment difference* (95% CI)	-91.7 (-120.1, -63.4)	

* Based on mixed-effect model for repeated measures.
** Difference in rates and associated 95% CI are calculated using Miettinen and Nurminen method adjusting for stratification factors.
Abbreviations: CI = confidence interval; FACIT = Functional Assessment of Chronic Illness Therapy

Figure 1: Mean change in haemoglobin level from baseline to week 12 (all randomised patients)



Results at week 24 were consistent with those at week 12 and support maintenance of the effect. Among the 55 patients with PNH who received danicopan for 24 weeks, the LS mean change in Hgb from baseline to week 24 was 2.95 g/dL [1.83 mmol/L] (95% CI: 2.42 [1.50], 3.48 [2.16]), 69.1% maintained transfusion avoidance through week 24 and 41.8% had a Hgb increase of ≥ 2 g/dL [1.2 mmol/L] in the absence of transfusion at week 24. These patients also had consistent

improvement in FACIT-Fatigue scores that was maintained through 24 weeks, the mean change from baseline was 6.19 (95% CI: 4.10, 8.29).

A total of 80 patients entered the LTE, during which all patients received danicopan. Efficacy results up to Week 72 are consistent with those at Week 12 and Week 24. In patients who received danicopan for 72 weeks (N = 38), the mean change in Hgb from Baseline to Week 72 was 2.81 g/dL [1.74 mmol/L].

Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with Voydeya in one or more subsets of the paediatric population in the treatment of PNH (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Absorption

Danicopan is rapidly absorbed after oral dosing, with mean time to maximum observed concentration occurring at about 3 hours post dose. Over the dose range of 200 mg to 800 mg, C_{max} increased in a less than dose-proportional manner, likely due to solubility-limited absorption.

When danicopan was administered with a high-fat meal, AUC and C_{max} were approximately 25%, and 93% higher, respectively, compared to the fasted state. Median T_{max} was comparable when danicopan was administered in the non-fasted or fasted state at approximately 3.0 and 2.5 hours, respectively (see section 4.2).

Danicopan is highly permeable and a P-gp substrate *in vitro* but with low efflux ratio. The oral exposure of danicopan does not appear to be affected by P-gp efflux in the gastrointestinal tract. Danicopan is not a substrate of BCRP, OATP1B1, or OATP1B3.

Distribution

Danicopan is highly bound to human plasma proteins (91.5% to 94.3%) and is mainly distributed in plasma with a ratio of whole blood to plasma mean $AUC_{0-\infty}$ of 0.545. Danicopan plasma concentrations appeared to decline in a biphasic manner after T_{max}. The estimated oral apparent volume of distribution for a 75 kg person using the population-PK model was 168 L for Vc/F and 234 L for Vp/F (402 L total), suggesting a moderate distribution of danicopan to peripheral tissue.

Biotransformation

Danicopan is extensively metabolised (96%) after oral dosing via oxidation, reduction, and hydrolysis pathways, with amide hydrolysis identified as the major pathway of elimination. Metabolism by CYP-mediated mechanisms is minimal.

Elimination

Following oral administration, the principal route of elimination is in the faeces (approximately 69% of the administered dose, compared to approximately 25% of the administered dose in urine). In the population pharmacokinetic (PK) analysis in patients with PNH who have clinically significant EVH, the $t_{½}$ has an estimated mean value of 7.91 hours.

Special populations

No clinically significant differences in the pharmacokinetics of danicopan were observed based on sex, age, or race based on population PK assessment.

Renal impairment
Following oral administration of danicopan 200 mg in subjects with severe renal impairment (eGFR < 30 mL/min/1.73 m^2), the extent of danicopan exposure (AUC) increased by approximately 50% as compared to subjects with normal renal function. Renal excretion is not the major route for clearing danicopan from the body, even in subjects with normal renal function (see section 4.2).

Hepatic impairment
No significant difference in danicopan exposure is observed in subjects with moderate hepatic impairment (Child-Pugh Class B) as compared to subjects with normal hepatic function (see section 4.2). Studies have not been conducted in patients with severe hepatic impairment (Child-Pugh Class C).

5.3 Preclinical safety data

In the 6-month toxicity study in rats (species not pharmacologically sensitive to danicopan), hypertrophy in liver, thyroid and adrenal gland was observed at doses of 1000 mg/kg/day (~26-fold above human exposure at 200 mg three times a day based on AUC).

In the 9-month toxicity study in dogs, dose of 150 mg/kg/day was not tolerated. Target organ effects were observed in the liver consistent with hepatobiliary cholestasis and included bile duct hypertrophy/hyperplasia and pigment accumulation in Kupffer cell and hepatocyte, consistent with bile pigment. Increases in AST, ALT, ALP, GGT, and TBIL correlated with histological findings in the liver. Hypertrophy/hyperplasia of the bile duct was observed in males at doses greater than or equal to 75 mg/kg/day (~5-fold above human exposure at 200 mg three times a day based on AUC). However, the findings at the dose of 75 mg/kg/day were less in severity and magnitude and did not have correlative clinical pathology findings.

Genotoxicity/carcinogenicity

Danicopan was not genotoxic in the Ames bacterial reverse mutation assay, *in vitro* micronucleus assay in human peripheral blood lymphocytes or in the *in vivo* micronucleus assay in rats.

Danicopan was not carcinogenic in the 6-month carcinogenicity study in TgRasH2 mice and in the 2-year rat carcinogenicity study. However, in the rat study a higher incidence of endometrial epithelium neoplasmas at the highest dose of 500 mg/kg/day compared to control animals was observed although the rat strain can have a high background incidence of endometrial carcinomas. The clinical relevance of this finding is unknown.

Reproductive/developmental toxicity

In the fertility and early embryonic development study in rabbits, reduced male and female reproductive performance was observed at 500 mg/kg/day, a dose associated at poor tolerability. The NOAEL for male and female reproductive toxicity was considered to be 250 mg/kg/day (7.2- and 8.8-fold above the human exposure).

In the pre- and post-natal development study in rabbits, in the F1 males, a decrease (19, 20 and 18%) in cauda epididymal sperm concentration relative to controls was observed in all dose groups (50, 125 and 250 mg/kg/day, respectively), being statistically significant only in the low and mid dose groups. This did not impact the reproductive capability of the F1 generation.

There were no effects on early embryonic development and foetal development in rabbits up to mean maternal systemic exposure ~20-fold above human exposure or during post-natal development. In the rats, there were no effects on embryo-foetal development up to maternal exposure ~30-fold above the human exposure at 200 mg three times a day.

Excretion in milk

Danicopan was excreted into the milk of lactating rabbits following oral administration from lactation Day 4 to 10, with milk concentrations approximately 5 and 3.5 times higher compared to maternal plasma concentrations at 50 and 250 mg/kg/day, respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Lactose monohydrate
Cellulose, microcrystalline
Croscarmellose sodium
Sodium laurilsulfate
Magnesium stearate
Silica, hydrophobic colloidal
Hypromellose acetate succinate

Film-coating

Polyvinyl alcohol
Titanium dioxide (E171)
Macrogol 4000
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months in high-density polyethylene (HDPE) bottle
After first opening the bottle: 48 days

2 years in polyvinyl chloride (PVC)/polychlorotrifluoroethylene (PCTFE) / PVC blisters

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Bottle

HDPE bottles containing 90 film-coated tablets with desiccant and child resistant seal. Each pack contains 180 film-coated tablets.

The following pack sizes are available:

- Packs containing 1 bottle of 90 × 50 mg film-coated tablets and 1 bottle of 90 × 100 mg film-coated tablets.

- Packs containing 2 bottles of 90 × 100 mg film-coated tablets.

Blister

PVC/PCTFE/PVC blister. Each pack contains 168 film-coated tablets.

The following pack sizes are available:

- Pack containing 4 blister wallet cards (child resistant), each containing 21 × 50 mg film-coated tablets and 21 × 100 mg film-coated tablets.

- Pack containing 4 blister wallet cards (child resistant), each containing 42 × 100 mg film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Alexion Europe SAS
103-105 rue Anatole France
92300 Levallois-Perret
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1792/001
EU/1/24/1792/002
EU/1/24/1792/003
EU/1/24/1792/004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 April 2024

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Alexion Pharma International Operations Limited
College Business and Technology Park
Blanchardstown Road North
Dublin 15
D15 R925
Ireland

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR 50 MG AND 100 MG FILM-COATED TABLETS (BLISTER)

1. NAME OF THE MEDICINAL PRODUCT

Voydeya 50 mg film-coated tablets
Voydeya 100 mg film-coated tablets
danicopan

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 50 mg film-coated tablet contains 50 mg of danicopan.
Each 100 mg film-coated tablet contains 100 mg of danicopan.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate.
See the leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets
4 blister wallet cards each containing 21 × 50 mg tablets and 21 × 100 mg tablets
For a 150 mg dose

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alexion Europe SAS
103-105, rue Anatole France
92300 Levallois-Perret
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1792/002

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Voydeya 50 mg
Voydeya 100 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BLISTER WALLET FOR 50 MG AND 100 MG FILM-COATED TABLETS

1. NAME OF THE MEDICINAL PRODUCT

Voydeya 50 mg film-coated tablets
Voydeya 100 mg film-coated tablets
danicopan

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 50 mg film-coated tablet contains 50 mg of danicopan.
Each 100 mg film-coated tablet contains 100 mg of danicopan.

3. LIST OF EXCIPIENTS

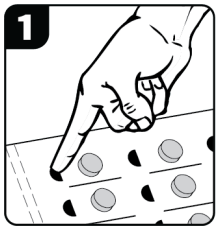
Contains lactose monohydrate.

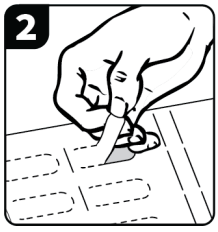
4. PHARMACEUTICAL FORM AND CONTENTS

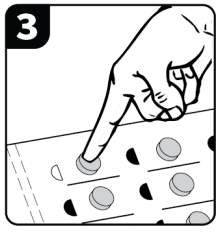
21 × 50 mg film-coated tablets and 21 × 100 mg film-coated tablets
For a 150 mg dose

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use







PUSH: Push through black half-circle.
PEEL: Turn card over and peel tab to expose foil.
REMOVE: Push on plastic blister to remove tablets.

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7

Dose 1
Dose 2
Dose 3

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alexion Europe SAS
103-105, rue Anatole France
92300 Levallois-Perret
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1792/002

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Voydeya 50 mg film-coated tablets
Voydeya 100 mg film-coated tablets
danicopan

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Alexion Europe SAS

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR 100 MG FILM-COATED TABLETS (BLISTER)

1. NAME OF THE MEDICINAL PRODUCT

Voydeya 100 mg film-coated tablets
danicopan

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 100 mg of danicopan.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate.
See the leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets
4 blister wallet cards each containing 42 × 100 mg tablets
For a 200 mg dose

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alexion Europe SAS
103-105, rue Anatole France
92300 Levallois-Perret
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1792/004

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Voydeya 100 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BLISTER WALLET FOR 100 MG FILM-COATED TABLETS

1. NAME OF THE MEDICINAL PRODUCT

Voydeya 100 mg film-coated tablets
danicopan

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 100 mg of danicopan.

3. LIST OF EXCIPIENTS

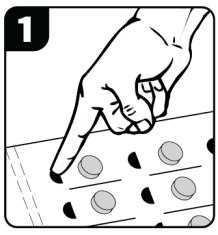
Contains lactose monohydrate.

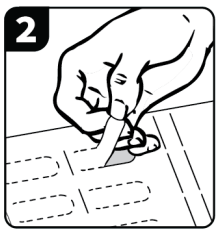
4. PHARMACEUTICAL FORM AND CONTENTS

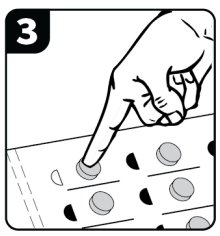
42 film-coated tablets
For a 200 mg dose

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use







PUSH: Push through black half-circle.

PEEL: Turn card over and peel tab to expose foil.
REMOVE: Push on plastic blister to remove tablets.

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7

Dose 1
Dose 2
Dose 3

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alexion Europe SAS
103-105, rue Anatole France
92300 Levallois-Perret
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1792/004

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Voydeya 100 mg film-coated tablets
danicopan

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Alexion Europe SAS

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR 50 MG AND 100 MG FILM-COATED TABLETS (BOTTLE)

1. NAME OF THE MEDICINAL PRODUCT

Voydeya 50 mg film-coated tablets
Voydeya 100 mg film-coated tablets
danicopan

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 50 mg film-coated tablet contains 50 mg of danicopan.
Each 100 mg film-coated tablet contains 100 mg of danicopan.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate.
See the leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets
1 bottle of 90 × 50 mg tablets and 1 bottle of 90 × 100 mg tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not swallow the desiccant.

8. EXPIRY DATE

EXP
After first opening the bottle, use within 48 days.

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alexion Europe SAS
103-105, rue Anatole France
92300 Levallois-Perret
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1792/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Voydeya 50 mg
Voydeya 100 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE FOR 50 MG FILM-COATED TABLETS

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Voydeya 50 mg film-coated tablets
danicopan
Oral use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

90 tablets

6. OTHER

Contains lactose monohydrate.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE FOR 100 MG FILM-COATED TABLETS

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Voydeya 100 mg film-coated tablets
danicopan
Oral use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

90 tablets

6. OTHER

Contains lactose monohydrate.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR 100 MG FILM-COATED TABLETS (BOTTLE)

1. NAME OF THE MEDICINAL PRODUCT

Voydeya 100 mg film-coated tablets
danicopan

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 100 mg of danicopan.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate.
See the leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets
2 bottles of 90 × 100 mg tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not swallow the desiccant.

8. EXPIRY DATE

EXP
After first opening the bottle, use within 48 days.

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alexion Europe SAS
103-105, rue Anatole France
92300 Levallois-Perret
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1792/003

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Voydeya 100 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Voydeya 50 mg film-coated tablets
Voydeya 100 mg film-coated tablets
danicopan

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Voydeya is and what it is used for

What is Voydeya
Voydeya contains the active substance danicopan. Danicopan blocks a protein called factor D, which is part of the body's defence system called the 'complement system'. By blocking factor D, danicopan prevents the complement system from instructing your body's immune system to destroy your red blood cells (haemolysis).

What is Voydeya used for
Voydeya is used to treat adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are being treated with another type of PNH medicine called a C5 inhibitor (ravulizumab or eculizumab) and have residual haemolytic anaemia (low red blood cell count due to their destruction by the body's immune system). Voydeya is given in addition to ravulizumab or eculizumab.

2. What you need to know before you take Voydeya

Do not take Voydeya
- If you are allergic to danicopan or any of the other ingredients of this medicine (listed in section 6).
- If you have not been vaccinated against meningococcal infection.
- If you have meningococcal infection.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine.

Serious infections
Before starting Voydeya, inform your doctor if you have any infections.

Meningococcal infections

Because the medicine targets the complement system, which is part of the body's defences against infections, the use of this medicine may increase your risk of meningococcal infection caused by *Neisseria meningitidis*. These are severe infections affecting the linings of the brain which can cause inflammation of the brain (encephalitis) and can spread throughout the blood and body (sepsis).

Talk to your doctor before you start taking this medicine to be sure that you are up-to-date with your vaccinations against *Neisseria meningitidis* at least 2 weeks before beginning therapy. If you cannot be vaccinated 2 weeks beforehand, your doctor will prescribe antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated. If you have had these vaccines in the past, you might still need additional vaccinations (booster) before starting Voydeya. You should also be aware that vaccination may not always prevent this type of infection.

The following are symptoms of a meningococcal infection. If you experience any of these symptoms, you should immediately inform your doctor:
- headache with nausea (feeling sick) or vomiting
- headache and fever
- headache with a stiff neck or stiff back
- fever
- fever and rash
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light

Treatment for meningococcal infection while travelling

If you are travelling in a region where you are unable to contact your doctor or will be temporarily unable to receive medical treatment, your doctor may prescribe an antibiotic against *Neisseria meningitidis* to bring with you. If you experience any of the symptoms described above, you should take the course of antibiotics as prescribed. You should bear in mind that you should still see a doctor as soon as possible, even if you feel better after having taken the antibiotics.

Other serious infections

In accordance with national recommendations, your doctor might consider that you need supplementary measures to prevent any other infections.

Kidney problems
Talk to your doctor if you have severe kidney problems. Your doctor may revise your dose and monitor you during treatment with Voydeya due to higher level of danicopan in the blood.

Low body weight
Talk to your doctor if you have a low body weight of less than 60 kg, your doctor may monitor you during treatment with Voydeya due to higher level of danicopan in the blood.

Blood tests
The medicine may increase the amount of some liver enzymes in your blood. Your doctor will do some blood tests to check your liver before starting treatment. Voydeya is not recommended in patients with severe hepatic impairment.

Children and adolescents
Do not give this medicine to children under 18 years of age as no data on its safety and effectiveness are available in this age group.

Other medicines and Voydeya
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, you should tell your doctor if you are taking any of the following medicines so that the doctor can decide if your treatment needs to change:
- Dabigatran and edoxaban, medicines to prevent blood clots
- Digoxin, a medicine to treat irregular heartbeat
- Fexofenadine, a medicine to treat allergy symptoms
- Tacrolimus, a medicine used to suppress the immune system
- Rosuvastatin, a medicine used to lower blood cholesterol levels
- Sulfasalazine, a medicine used to treat to treat inflammatory bowel disease or rheumatoid arthritis

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The effects of the medicine on an unborn child are not known. As a precautionary measure, you should not take Voydeya if you are pregnant.
This medicine may be passed into breast milk. Do not use Voydeya during breast-feeding.
Breast-feeding should not be started until 3 days after you stop taking Voydeya.

Driving and using machines
Voydeya has no or negligible influence on the ability to drive or use machines.

Voydeya contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Voydeya contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Voydeya

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

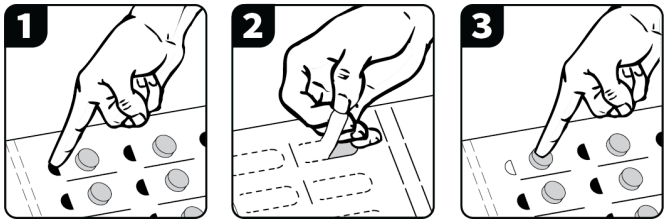
How much to take
The recommended starting dose of Voydeya is 150 mg three times a day, approximately 8 hours apart (plus or minus 2 hours). Your doctor may decide to increase the dose to 200 mg three times a day depending on how you respond to treatment.

If you have severe kidney disease, the recommended starting dose of Voydeya is 100 mg three times a day, approximately 8 hours apart (plus or minus 2 hours). Your doctor may decide to increase the dose to 150 mg three times a day depending on how you respond to treatment.

Depending on the dose prescribed, the number of tablets per dose is as follows:
- 100 mg: one 100 mg tablet
- 150 mg: one 50 mg tablet and one 100 mg tablet
- 200 mg: two 100 mg tablets

Taking this medicine
You should take your tablets with food (meal or snack).

If you have been given Voydeya in a blister pack, follow these instructions to take the tablets out of the packaging:
1. Push through black half-circle.
2. Turn card over and peel tab to expose foil.
3. Push on plastic blister to remove tablets.



If you take more Voydeya than you should
If you have taken more Voydeya than you should, contact your doctor immediately. Take the medicine pack with you so that you can easily describe what you have taken.

If you forget to take Voydeya
If you miss a dose, take it as soon as possible. If it is almost time to take your next dose, skip the missed dose. Then take the next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Voydeya
Do not stop treatment with Voydeya unless your doctor tells you to. If you stop taking this medicine, symptoms of residual haemolytic anaemia may come back. If you have to stop taking this medicine, your doctor will reduce the dose gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If you experience any of the meningococcal infection symptoms (see section 2 Meningococcal infection symptoms), you should immediately inform your doctor:
- headache with nausea (feeling sick) or vomiting
- headache and fever
- headache with a stiff neck or stiff back
- fever
- fever and rash
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light

Other side effects

Very common (may affect more than 1 in 10 people)
- Fever or high temperature (pyrexia)
- Headache
- Blood test showing increased level of liver enzymes
-

Common (may affect up to 1 in 10 people)
- Arm and leg pain (pain in extremities)
- Vomiting
- High blood pressure

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Voydeya

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle or blister wallet after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. After first opening the bottle, use the medicine within 48 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Voydeya contains
The active substance is danicopan. Each film-coated tablet contains 50 mg or 100 mg danicopan.

The other ingredients are:
- Tablet core: lactose monohydrate, cellulose, microcrystalline, croscarmellose sodium, sodium laurilsulfate, magnesium stearate, silica, hydrophobic colloidal, hypromellose acetate succinate. See section 2 Voydeya contains lactose monohydrate and sodium.
- Film-coating: polyvinyl alcohol, titanium dioxide (E171), macrogol 4000, talc.

What Voydeya looks like and contents of the pack
Voydeya 50 mg film-coated tablets are white to off-white, round film-coated tablets with “DCN” above “50” debossed on one side, and plain on the other side.
Voydeya 100 mg film-coated tablets are white to off-white, round film-coated tablets with “DCN” above “100” debossed on one side, and plain on the other side.

The tablets may be supplied either in a bottle or in a blister pack.

Bottle
- Voydeya 50 mg film-coated tablets + 100 mg film-coated tablets: each pack contains 180 tablets (1 bottle of 90 × 50 mg tablets and 1 bottle of 90 × 100 mg tablets).
- Voydeya 100 mg film-coated tablets: each pack contains 180 tablets (2 bottles of 90 × 100 mg tablets).

Blister
- Voydeya 50 mg film-coated tablets + 100 mg film-coated tablets: each pack contains 168 tablets (4 blister wallet cards each containing 21 × 50 mg tablets and 21 × 100 mg tablets).
- Voydeya 100 mg film-coated tablets: each pack contains 168 tablets (4 blister wallet cards each containing 42 × 100 mg tablets).

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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92300 Levallois-Perret
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Manufacturer
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Dublin 15
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Ireland

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu. There are also links to other websites about rare diseases and treatments.