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Questions and answers on Haldol and associated names (haloperidol tablets, oral solutions and injectable solution)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 23 February 2017, the European Medicines Agency completed a review of Haldol. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Haldol in the European Union (EU).

What is Haldol?

Haldol is an antipsychotic medicine used in adults and children for a number of mental and other brain disorders including schizophrenia, mania (feeling elated or over-excited), aggression, Tourette's syndrome and tics (repeated and uncontrollable movements) and choreatic movements (jerky and uncontrolled movements mainly of the face and hands). It is also used for the treatment of vomiting.

Haldol and associated names (such as Aloperidin and Serenase) is marketed in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Malta, the Netherlands, Portugal, Romania, Sweden and United Kingdom, and also in Iceland and Norway. It contains the active substance haloperidol and is available as tablets, oral solutions, and injection. It is also available in the EU as generic haloperidol.

The companies that market these medicines include Janssen-Cilag Ltd and associated companies.

Why was Haldol reviewed?

Haldol is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Haldol was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

On 18 June 2014, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Haldol and associated names in the EU.

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What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed that Haldol tablets and oral solutions can be used as follows.

In adults, for:

- treatment of schizophrenia and schizoaffective disorder;
- acute treatment of delirium when non-pharmacological treatments (treatments that do not involve medicines) have not worked;
- treatment of moderate to severe manic episodes associated with bipolar I disorder;
- treatment of acute psychomotor agitation associated with psychotic disorder or manic episodes of bipolar I disorder;
- treatment of persistent aggression and psychotic symptoms in patients with moderate to severe Alzheimer's dementia and vascular dementia when non-pharmacological treatments have not worked and when there is a risk of harm to the patient or to others;
- treatment of tic disorders, including Tourette's syndrome, in patients with severe impairment after educational and psychological treatments and other medicines have not worked;
- treatment of mild to moderate chorea in Huntington's disease, when other medicines do not work or have unacceptable side effects.

In children and adolescents, for:

- schizophrenia in adolescents aged 13 to 17 years when other medicines have not worked or cause unacceptable side effects;
- persistent, severe aggression in children and adolescents aged 6 to 17 years with autism or pervasive developmental disorders, when other treatments have not worked or cause unacceptable side effects;
- tic disorders, including Tourette's syndrome, in children and adolescents aged 10 to 17 years with severe impairment after educational and psychological treatments and other medicines have not worked.

The CHMP agreed that Haldol injection can be used in adults as follows:

- for rapid control of severe acute psychomotor agitation linked to psychotic disorder or manic episodes of bipolar I disorder when medicines cannot be given by mouth;
- for short-term treatment of delirium when non-pharmacological treatments have not worked;
- for treatment of mild to moderate chorea in Huntington's disease, when other medicines are ineffective or have unacceptable side effects and when medicines cannot be given by mouth;
- alone or with other medicines, for prevention of nausea and vomiting after surgery in those who are at moderate to high risk, when other medicines do not work or have unacceptable side effects;

- with other medicines, for treatment of nausea and vomiting after surgery when other medicines do not work or have unacceptable side effects.

The CHMP agreed that Haldol should no longer be used for the treatment of delirium, delusions or hallucinations which follow alcohol withdrawal because the medicine has not proven effective for treating the underlying condition and there is inadequate evidence that it is of benefit when used with a benzodiazepine.

4.2 Posology and method of administration

The CHMP harmonised the starting, maintenance and maximum doses for each of the different uses of Haldol in adults, elderly patients and in children and adolescents. The CHMP agreed that starting dose in the elderly should be as low as possible and harmonised advice on the starting doses of Haldol in those with liver or kidney disorders.

4.3 Contra-indications

The CHMP agreed to harmonisation of Haldol's contra-indications. In particular, Haldol must not be used in patients with heart disorders such as certain heart-rhythm problems, heart failure and recent heart attack, and with central nervous depression (reduced brain activity that slows down breathing and heart rate and reduces alertness).

4.4 Special warnings and precautions

The CHMP harmonised the SmPC to include a warning that patients with bipolar disorders may suffer sudden depression, calling for close supervision of such patients. The section was also harmonised with information on when Haldol's side effects on movement might appear, details on mortality in the elderly, and effects on the heart and the brain. The SmPC recommends caution in patients who have a high level of the hormone prolactin and in those who have tumours that are worsened by prolactin.

Other changes

The CHMP harmonised other sections of the SmPC including interactions between Haldol and other medicines (section 4.5), information on pregnancy, lactation and fertility (section 4.6) and added angioedema as a side effect (section 4.8).

The amended information to doctors and patients is available here.

The European Commission issued a decision on this opinion on 28/04/2017.