PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR UROREC (SILODOSIN)

This is a summary of the risk management plan (RMP) for Urorec (silodosin). The RMP details important risks of Urorec, how these risks can be minimised, and how more information will be obtained about Urorec's risks and uncertainties (missing information).

Urorec's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Urorec should be used.

This summary of the RMP for Urorec should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones are included in updates of Urorec 's RMP.

I. The medicine and what it is used for

Urorec is authorised for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) (see SmPC for the full indication). It contains silodosin as the active substance and it is given orally as a 4mg or an 8 mg hard capsule.

Further information about the evaluation of Urorec's benefits can be found in Urorec's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Urorec, together with measures to minimise such risks and the proposed studies for learning more about Urorec's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Urorec is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Urorec. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table VI-1 Summary table of Safety concerns

Important identified risks	None
Important potential risks	Misdiagnosis of prostate cancer
Important missing information	None

II.B Summary of important risks

Important potential risk: Misdiagnosis of prostate cancer	
Evidence for linking the risk to the medicine	Due to the fact that the symptoms of prostate cancer and BPH can be very similar, there is the potential risk of a delay in the appropriate treatment of prostate cancer.
Risk factors and risk groups	Patients with increased PSA levels (>4.0 ng/ml)
Risk minimisation measures	Routine risk minimisation activities recommending specific clinical measures to address the risk: • SmPC section 4.4 • PL section 2.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligations of silodosin.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for silodosin.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR SILODYX (SILODOSIN)

This is a summary of the risk management plan (RMP) for Silodyx (silodosin). The RMP details important risks of Silodyx, how these risks can be minimised, and how more information will be obtained about Silodyx's risks and uncertainties (missing information).

Silodyx's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Silodyx should be used.

This summary of the RMP for Silodyx should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones are included in updates of Silodyx 's RMP.

I. The medicine and what it is used for

Silodyx is authorised for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) (see SmPC for the full indication). It contains silodosin as the active substance and it is given orally as a 4mg or an 8 mg hard capsule.

Further information about the evaluation of Silodyx's benefits can be found in Silodyx's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Silodyx, together with measures to minimise such risks and the proposed studies for learning more about Silodyx's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Silodyx is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Silodyx. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table VI-1 Summary table of Safety concerns

Important identified risks	None
Important potential risks	Misdiagnosis of prostate cancer
Important missing information	None

II.B Summary of important risks

Important potential risk: Misdiagnosis of prostate cancer	
Evidence for linking the risk to the medicine	Due to the fact that the symptoms of prostate cancer and BPH can be very similar, there is the potential risk of a delay in the appropriate treatment of prostate cancer.
Risk factors and risk groups	Patients with increased PSA levels (>4.0 ng/ml)
Risk minimisation measures	Routine risk minimisation activities recommending specific clinical measures to address the risk: • SmPC section 4.4 • PL section 2.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligations of silodosin.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for silodosin.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR SILODOSIN RECORDATI

This is a summary of the risk management plan (RMP) for Silodosin Recordati. The RMP details important risks of Silodosin Recordati, how these risks can be minimised, and how more information will be obtained about Silodosin Recordati's risks and uncertainties (missing information).

Silodosin Recordati's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Silodosin Recordati should be used.

This summary of the RMP for Silodosin Recordati should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones are included in updates of Silodosin Recordati 's RMP.

I. The medicine and what it is used for

Silodosin Recordati is authorised for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) (see SmPC for the full indication). It contains silodosin as the active substance and it is given orally as a 4mg or an 8 mg hard capsule.

Further information about the evaluation of Silodosin Recordati’s benefits can be found in Silodosin Recordati’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Silodosin Recordati, together with measures to minimise such risks and the proposed studies for learning more about Silodosin Recordati's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Silodosin Recordati is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Silodosin Recordati. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table VI-1 Summary table of Safety concerns

Important identified risks	None
Important potential risks	Misdiagnosis of prostate cancer
Important missing information	None

II.B Summary of important risks

Important potential risk: Misdiagnosis of prostate cancer	
Evidence for linking the risk to the medicine	Due to the fact that the symptoms of prostate cancer and BPH can be very similar, there is the potential risk of a delay in the appropriate treatment of prostate cancer.
Risk factors and risk groups	Patients with increased PSA levels (>4.0 ng/ml)
Risk minimisation measures	Routine risk minimisation activities recommending specific clinical measures to address the risk: • SmPC section 4.4 • PL section 2.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligations of silodosin.

II.C.2 Other studies in post-authorisation development plan