

**Souhrn plánu řízení rizik podle § 99 odst. 8 písm. a) zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů (1)**

***Pomalidomide Abdi 1 mg tvrdé tobolky***

***Pomalidomide Abdi 2 mg tvrdé tobolky***

***Pomalidomide Abdi 3 mg tvrdé tobolky***

***Pomalidomide Abdi 4 mg tvrdé tobolky***

Administrativní informace:

|                                  |  |
|----------------------------------|--|
| Léčivá látka/látky               | pomalidomid  |
| Léková forma/formy               | tvrdá tobolka                                      |
| Síla/síly                        | 1 mg, 2 mg, 3 mg, 4 mg                             |
| Držitel rozhodnutí o registraci  | Abdi Farma GmbH, Heppenheim, Německo               |
| Registrační číslo/čísla          | 44/349/23-C, 44/350/23-C, 44/351/23-C, 44/352/23-C |
| Verze a datum plánu řízení rizik | verze 0.3, 24. listopad 2024                       |

Následující výňatek z plánu řízení rizik (RMP) výše uvedeného léčivého přípravku/léčivých přípravků je souhrnem podstatných informací uvedených ve zmíněném RMP. RMP popisuje opatření, která mají být přijata, aby bylo zajištěno, že tento léčivý přípravek/tyto léčivé přípravky budou používány co nejbezpečněji. Souhrn RMP je potřeba číst spolu se schváleným souhrnem údajů o přípravku/přípravcích a příbalovou informací.

Tento souhrn RMP připravil Státní ústav pro kontrolu léčiv za účelem splnění své zákonné povinnosti týkající se transparentnosti vůči veřejnosti.

1) [Zákon č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů](#)

# Summary of risk management plan for Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules (Pomalidomide)

This is a summary of the risk management plan (RMP) for Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules. The RMP details important risks of Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules, how these risks can be minimized, and how more information will be obtained about Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules' risks and uncertainties (missing information).

Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules should be used.

Important new concerns or changes to the current ones will be included in updates of Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules' RMP.

## **I. The medicine and what it is used for**

Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules in combination with bortezomib and dexamethasone are authorised for the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.

Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules in combination with dexamethasone are authorised for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. (See SmPC for full indication).

It contains pomalidomide as the active substance and it is given by oral route of administration.

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

Important risks of Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules, together with measures to minimise such risks and the proposed studies for learning more about Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules' 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 PL 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 the case of Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

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.

### **II.A List of important risks and missing information**

Important risks of Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules. 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);

| <b>List of important risks and missing information</b> |  |
|--|--|
| Important identified risks                             | <ul style="list-style-type: none"> <li>• Teratogenicity</li> <li>• Severe infection due to neutropenia and pancytopenia</li> <li>• Thrombocytopenia and bleeding</li> <li>• Cardiac failure</li> <li>• Non-melanoma skin cancer</li> </ul> |
| Important potential risks                              | <ul style="list-style-type: none"> <li>• Other second primary malignancies</li> <li>• Cardiac arrhythmia</li> </ul>  |
| Missing information                                    | None   |

### **II.B Summary of important risks**

| <b>Teratogenicity</b>      |   |
|----------------------------|---|
| Risk minimisation measures | <p><b>Routine risk minimisation measures:</b></p> <ul style="list-style-type: none"> <li>• SmPC sections 4.3, 4.4, 4.5, 4.6, 4.8 and 5.3</li> <li>• PL sections 2 and 3</li> <li>• Prescription only medicine</li> </ul> <p><b>Additional risk minimisation measures:</b></p> <ul style="list-style-type: none"> <li>• PPP</li> </ul> |

|  |  |
|--|--|
|  | <ul style="list-style-type: none"> <li>• HCP kit to include booklet.</li> <li>• Treatment algorithm, pregnancy reporting form, Patient Card and/or equivalent tool, and Patient Brochure.</li> <li>• Educational Programme</li> <li>• Therapy management <ul style="list-style-type: none"> <li>○ Criteria for determining women of childbearing potential, contraceptive measures and pregnancy testing for women of childbearing potential.</li> <li>○ Advice in SmPC and educational materials.</li> <li>○ System to ensure appropriate measures have been completed</li> </ul> </li> <li>• Patient Card to document childbearing status, counselling and pregnancy testing.</li> </ul> |
|--|--|

| <b>Thrombocytopenia and bleeding</b> |  |
|--------------------------------------|--|
| <b>Risk minimisation measures</b>    | <p><b>Routine risk minimisation measures:</b></p> <ul style="list-style-type: none"> <li>• SmPC section 4.8</li> <li>• PL section 4</li> <li>• Prescription only medicine</li> </ul> <p><b>Additional risk minimisation measures:</b></p> <ul style="list-style-type: none"> <li>• HCP Educational Materials</li> <li>• Patient brochure.</li> </ul> |

| <b>Cardiac failure</b>            |   |
|-----------------------------------|---|
| <b>Risk minimisation measures</b> | <p><b>Routine risk minimisation measures:</b></p> <ul style="list-style-type: none"> <li>• SmPC section 4.8</li> <li>• PL section 4</li> <li>• Prescription only medicine</li> </ul> <p><b>Additional risk minimisation measures:</b></p> <ul style="list-style-type: none"> <li>• HCP Educational Materials</li> </ul> |

## ***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 obligation of Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules.

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

There are no studies required for Pomalidomide Abdi 1 mg, 2 mg, 3 mg, 4 mg Hard Capsules.