

## VI.2 Elements for a Public Summary

### VI.2.1 Overview of disease epidemiology

Diarrhoea, or loose and abnormally frequent stools, is one of the most common health problems in people of all ages. Diarrhoea is usually caused by a stomach virus and usually stops after a few days. Diarrhoea can be caused by many other factors (e.g. medicines, food poisoning) and can be sudden (acute) or long-lasting (chronic).

Chronic diarrhoea is less common than acute diarrhoea and is more common in the elderly and people with pre-existing medical conditions.

Diarrhoea often causes stomach discomfort, bloating, gas, nausea and vomiting, and loss of fluids and salts, which can cause tiredness, dizziness, or drowsiness. Treatments include extra fluids, medicines to bind to substances in the intestine and make stools more solid and medicines to normalize intestinal movement.

### VI.2.2 Summary of treatment benefits

Loperamid Orifarm is a remedy used to stop diarrhea. Loperamide acts by inhibiting the intestinal movements, thereby facilitating an increase in absorption of water and minerals from the intestines. This results in the stool becoming firmer and less frequent.

### VI.2.3 Unknowns relating to treatment benefits

There is insufficient information on the use of loperamide in children under 12 years of age or in pregnant and breastfeeding women.

### VI.2.4 Summary of safety concerns

#### Important identified risks

Risk	What is known	Preventability
<ul style="list-style-type: none"><li>• <b>Blockage of the intestine (Ileus including paralytic ileus)</b></li></ul>	<p>Loperamide works by reducing intestinal movement, and also by normalizing the balance between absorption and secretion of water and electrolytes, making the stools more solid and less frequent.</p> <p>There is a risk that blockage of the intestinal movement may lead to more serious problems. It can usually be treated with appropriate medications and rarely can be fatal.</p>	<p>There is no specific measure to prevent the occurrence.</p> <p>The risk can be reduced by not allowing the product to be used in patients where inhibition of intestinal movement is to be avoided.</p> <p>Patients should stop taking loperamide if they have intestinal blockage, constipation, or swollen stomach.</p> <p>Patients with AIDS treated with loperamide for diarrhoea should have therapy stopped at the earliest signs of swollen stomach.</p>

<b>Risk</b>	<b>What is known</b>	<b>Preventability</b>
<ul style="list-style-type: none"> <li>• <b>Dilation of the colon (megacolon, toxic megacolon)</b></li> </ul>	<p>Loperamide works by reducing intestinal movement, and also by normalizing the balance between absorption and secretion of water and electrolytes, making the stools more solid and less frequent.</p> <p>There is a risk that reducing intestinal movement may lead to more serious problems such as severe constipation and dilation of the colon. Dilation of the colon can be treated with appropriate medications but the more serious form toxic dilation of the colon can be fatal.</p>	<p>There is no specific measure to prevent the occurrence.</p> <p>The risk can be reduced by not allowing the product to be used in patients where inhibition of intestinal movement is to be avoided.</p> <p>Patients should stop taking loperamide if they have intestinal blockage, constipation, or swollen stomach.</p> <p>Patients with AIDS treated with loperamide for diarrhoea should have therapy stopped at the earliest signs of swollen stomach.</p>
<ul style="list-style-type: none"> <li>• <b>Severe skin reactions</b></li> </ul>	<p>Allergic reactions to the active substance or to any of the excipients may occur.</p> <p>Serious allergic skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme) are listed as possible adverse reactions of rare frequency. Severe allergic skin reactions can result in shock and death.</p>	<p>There is no specific measure to prevent the occurrence.</p> <p>The risk can be reduced by not allowing the product to be used in patients with known allergy (hypersensitivity) to the active substance or to any of the excipients.</p>
<ul style="list-style-type: none"> <li>• <b>Serious cardiac events after abuse/misuse</b></li> </ul>	<p>Serious and potentially fatal cardiac events have been seen in patients after misuse/abuse of loperamide</p>	<p>Loperamide should not be used for a longer period than recommended or in higher doses.</p>

#### Important potential risks

<b>Risk</b>	<b>What is known (Including reason why it is considered a potential risk)</b>
<ul style="list-style-type: none"> <li>• <b>Prolonged use which may mask serious conditions that requires medical attention</b></li> </ul>	<p>Treatment with loperamide is only symptomatic and is not treating the cause of diarrhoea. Patients who have diarrhoea for a long period of time may have more serious underlying medical conditions which should be investigated and treated.</p>
<ul style="list-style-type: none"> <li>• <b>Use in patients whose liver doesn't work properly (hepatic impairment)</b></li> </ul>	<p>Patients with liver impairment may have increased levels of loperamide in the blood leading to toxicity in the central nervous system.</p>

#### Missing information

<b>Risk</b>	<b>What is known</b>
<ul style="list-style-type: none"> <li>• <b>Use in children below 12 years</b></li> </ul>	<p>The product should not be used in children below 12 years due to limited clinical study experience in this age group.</p>
<ul style="list-style-type: none"> <li>• <b>Use in pregnant and breast feeding women</b></li> </ul>	<p>There is insufficient clinical study experience on use in pregnant or breast feeding women.</p>

**VI.2.5 Summary of risk minimisation measures by safety concern**

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Loperamid Orifarm can be found at the homepage of the National Health Authority.

This medicine has no additional risk minimisation measures.

**VI.2.6 Planned post authorisation development plan**

None.

**VI.2.7 Summary of changes to the Risk Management Plan over time**

Not applicable as this is the initial risk management plan.