Package leaflet: Information for the user

Imolieve 2mg orodispersible tablet
For adolescents from 12 years of age and adults

Loperamide hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet

1. What Imolieve is and what it is used for
Imolieve is a medicine for the symptomatic treatment of acute diarrhoea in adolescents from 12 years of age and adults, unless the cause of the diarrhoea can be treated.

Loperamide must not be used for longer than 2 days except after medical advice and with medical monitoring.

2. What you need to know before you use Imolieve
DO NOT use Imolieve if:
- you are allergic to loperamide hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- your child is less than 12 years old (see also "Children" below)
- you are suffering from conditions in which slowing of intestinal passage must be avoided, e.g. abdominal distensions, constipation and intestinal obstruction
  Imolieve must be stopped immediately in the event of constipation, abdominal distension or intestinal obstruction (ileus).
- you are suffering from diarrhoea with fever and/or bloody stool
- you are suffering from diarrhoea occurring during or after the use of antibiotics
- you are suffering from chronic diarrhoeal illnesses. (These diseases may only be treated with loperamide hydrochloride after medical advice)
- you are suffering from an acute episode of ulcerative colitis (a form of inflammatory bowel disease)

Imolieve should only be taken after a medical advice if liver disease is present or persisted because the breakdown of loperamide may be delayed and the risk of side effects increased in patients with severe liver disease.

Warnings and precautions
Do not take this product for anything other than its intended use (see section 1) and never take more than the recommended amount (see section 3). Serious heart problems (symptoms of which include fast or irregular heartbeat), loss of consciousness and even death have been reported in patients who have taken too much loperamide, the active ingredient in Imolieve.

Talk to your doctor or pharmacist before taking Imolieve:
- if you have AIDS and are taking Imolieve for acute diarrhoea. At the first signs of a distended (bloated) abdomen, you should stop taking Imolieve and consult your doctor. There are isolated reports of constipation with an increased risk of severe inflammatory enlargement of the large intestine (toxic megacolon) in AIDS patients. These patients were suffering from inflammation of the colon (colitis) caused by viral and bacterial pathogens and were being treated with loperamide hydrochloride
- if you have a liver disease.

Ensure sufficient replacement of fluids and salts (electrolytes). This is the most important measure in the treatment of diarrhoea, which can cause major fluid and salt loss. This particularly applies to children. You can use Imolieve in conjunction with oral rehydration.

Imolieve stops diarrhoea without removing its cause. Whenever the cause of diarrhoea can be identified, it should be treated appropriately. You should not use Imolieve as a primary treatment if the cause of diarrhoea can be identified and treated. For this reason talk to your doctor.

Abuse and misuse of loperamide hydrochloride, the active substance of Imolieve, have been reported. Take Imolieve only for those reasons described in section 1.
Do not take Imolieve longer than 2 days. You may develop severe constipation if you use Imolieve in higher doses or longer than recommended.

If diarrhoea persists after two days of treatment with Imolieve, stop taking Imolieve and see a doctor.

Children
Children **under 2 years** of age **must not** be treated with medicines that contain the active substance loperamide.

Children between **2 and 12 years** of age may only be treated with medicines that contain the active substance loperamide **after medical advice**. The high loperamide content of Imolieve means that this medicine is not suitable for this age group. For this age group other dosage forms are available after medical prescription.

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

In particular, please talk to your doctor if you need to take one or more of the following medicines regularly or even occasionally:
- **ritonavir** (a medicine for the treatment of HIV infections)
- **itraconazole, ketoconazole** (a medicine for the treatment of fungal infections)
- **quinidine** (a medicine for heart rhythm problems)
- **gemfibrozil** (a medicine for the treatment of high blood fat levels)
- **desmopressin** (a medicine for the treatment of excessive urination)

It is to be expected that medicines with a similar mechanism of action as Imolieve may increase its effect and drugs that accelerate the gastrointestinal passage may reduce its effect.

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.

<u>Pregnancy</u>
Although no clear evidence of effects on the foetus were found in a limited number of women taking the active substance loperamide during pregnancy, you should not take Imolieve during pregnancy.

<u>Breast-feeding</u>
Do not take this medicine if you are breast-feeding as small amounts of the active substance in Imolieve

may pass into the breast milk. Talk to your doctor about a suitable treatment.

Driving and using machines
This medicine or acute diarrhoea itself may make you feel dizzy, tired or sleepy. If affected, do not drive or operate machinery.

Imolieve contains aspartame
This medicine contains 3 mg aspartame in each orodispersible tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to use Imolieve
Always use Imolieve exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Age	**Starting dose**	**Follow up dose**	**Maximum daily dose**
Adolescents from 12 years of age	1 tablet	1 tablet	4 tablets
Adults	2 tablets	1 tablet	6 tablets

- Begin treatment of acute diarrhoea with the starting dose.
- Thereafter the follow up dose should be taken after every loose stool.
- The maximum daily dose must not be exceeded.

Children under 12 years of age
Imolieve is not suitable for children under 12 years of age due to the high content of the active substance. For this purpose other dosage forms are available on medical prescription.

Method of administration
Imolieve is placed on the tongue. The tablet disintegrates immediately on the tongue and can be swallowed. No further fluid intake is required.

Duration of treatment
Do not take Imolieve for longer than 2 days without medical advice.

If diarrhoea persists after two days of treatment with Imolieve, stop taking it and see a doctor.
You should only be treated for more than 2 days with medicines containing loperamide hydrochloride after medical advice and follow-up monitoring.

Please talk to your doctor or pharmacist if you have the impression that the effect of Imolieve is too strong or too weak.

If you take more Imolieve than you should
Consult a doctor immediately, especially if you experience any of the following symptoms:
- rigidity of the body, uncoordinated movements, drowsiness (somnolence), pupil constriction (miosis), muscle stiffness, weak breathing
- increased heart rate, irregular heartbeat, changes to your heartbeat (these symptoms may have potentially serious, life-threatening consequences)
- constipation, intestinal obstruction (ileus) and difficulties passing urine

Children react more strongly to large amounts of Imolieve than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

Information for the physician
Signs of loperamide hydrochloride overdose may also occur after a relative overdose due to liver

dysfunction. Treatment depends on the symptoms of overdose and the clinical diagnosis.

ECG monitoring for QT interval prolongation should be conducted under medical surveillance.
If central nervous system symptoms occur after overdose, the opioid antagonist naloxone may be given as an antidote. As loperamide has a longer duration of effect than naloxone, repeated administration of naloxone may be needed. The patient should therefore be closely monitored for at least 48 hours, so that possible occurrence/recurrence of overdose symptoms can be recognised.

If you forget to take Imolieve
Do not take a double dose to make up for a forgotten dose.

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.

The most commonly reported side effects in clinical studies were constipation, flatulence, headache, nausea and dizziness.

If you experience any of the following (rare) side effects, which have been observed in relation to treatment with loperamide hydrochloride, stop using Imolieve and seek immediate medical help:
- hypersensitivity reactions, anaphylactic reactions (including anaphylactic shock), anaphylactoid reactions such as unexplained wheezing, shortness of breath which can be accompanied by skin rash or hives, passing out or swelling of face, tongue or throat
- rigidity of the body, abnormal increase in muscle tension, problems with coordination
- skin rashes which may be severe and include blistering and peeling of the skin (including Stevens Johnson syndrome, toxic epidermal necrolysis and erythema multiforme), swelling of skin or mucous membranes through fluid retention (angioedema)
- distended (swollen) abdomen
- intestinal obstruction (ileus including paralytic ileus), dilation of colon (megacolon including toxic megacolon). Signs include feeling bloated, vomiting, severe constipation, loss of appetite, and cramps
- loss of consciousness, reduced level of consciousness
- difficulties passing urine (urinary retention)

Not known (frequency cannot be estimated from the available data)
- upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis).

The other side effects are:

Common (may affect up to 1 in 10 people)
- constipation, nausea, flatulence
- dizziness, headache

Uncommon (may affect up to 1 in 100 people)
- drowsiness
- abdominal pain and discomfort, dry mouth
- upper abdominal pain, vomiting
- indigestion
- skin rash

Rare (may affect up to 1 in 1,000 people)
- narrowing of the pupils in your eye (miosis)
- burning tongue

- nettle rash, itching
- tiredness

Immediately after taking loperamide orodispersible tablets, some patients reported a temporary burning or prickling sensation on the tongue.

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:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Imolieve
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 the blister after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Imolieve contains
The active substance is: loperamide hydrochloride.

Each tablet contains 2 mg loperamide hydrochloride.

The other ingredients are: mannitol, aspartame, crospovidone, citric acid, silica colloidal anhydrous, spearmint (flavouring ingredients, modified food starch), talc, magnesium stearate.

What Imolieve looks like and contents of the pack
Imolieve 2 mg comprise of white to off white, circular, flat face, bevelled edge, uncoated orodispersible tablets, plain on both sides with a diameter of 7 mm.

Imolieve 2 mg orodispersible tablets is supplied in Aluminium/Aluminium blister of 6, 10 and 12 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
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This medicinal product is authorised in the Member States of the EEA under the following names:

Germany:	Loperamid AL 2 mg Schmelztabletten
France:	LOPERAMIDE EG LABO CONSEIL 2 mg, comprimé orodispersible
Ireland:	Imolieve 2 mg orodispersible tablets
Italy:	LOPERAMIDE EG
United Kingdom:	Care Diarrhoea Relief 2 mg orodispersible tablets

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