
This amendment: Response to Clinical Recommendation.

Date of original submission: 12 December 2016

IMODIUM® MELT TABLETS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

IMODIUM® MELT 2 mg TABLETS

Each tablet contains 2 mg loperamide hydrochloride.

Contains sweetener: Each tablet contains 0,75 mg aspartame.

Contains mannitol.

Sugar free.

Read all of this leaflet carefully because it contains important information for you.

IMODIUM® MELT TABLETS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take IMODIUM® MELT TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share IMODIUM® MELT TABLETS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve (after 48 hours).

What is in this leaflet

1. What IMODIUM® MELT TABLETS is and what it is used for.
2. What you need to know before you take IMODIUM® MELT TABLETS.
3. How to take IMODIUM® MELT TABLETS.
4. Possible side effects.

This amendment: Response to Clinical Recommendation.

Date of original submission: 12 December 2016

5. How to store IMODIUM® MELT TABLETS.
6. Contents of the pack and other information.

1. What IMODIUM® MELT TABLETS is and what it is used for

IMODIUM® MELT TABLETS is used to treat diarrhoea in adults and children 6 years and older. It contains loperamide hydrochloride, a substance that helps reduce diarrhoea by slowing down an overactive bowel. This allows water and salts that are usually lost in diarrhoea to be absorbed by your body.

2. What you need to know before you take IMODIUM® MELT TABLETS

Do not take IMODIUM® MELT TABLETS:

- if you or your child are hypersensitive (allergic) to loperamide hydrochloride or any of the other ingredients of IMODIUM® MELT TABLETS (see **What IMODIUM® MELT TABLETS contains**);
- if you or your child have acute dysentery (symptoms may include blood in your stools and fever);
- if you have a flare-up of an inflammatory bowel condition like ulcerative colitis or if you have inflammation of your bowels caused by bacterial infections;
- if you or your child have severe diarrhoea after taking antibiotics;
- if you or your child are constipated, or your stomach appears swollen (especially in children with severe dehydration).

IMODIUM® MELT TABLETS is contraindicated for use in children under the age of 6 years.

Warnings and precautions

Take special care with IMODIUM® MELT TABLETS:

This amendment: Response to Clinical Recommendation.

Date of original submission: 12 December 2016

- if you or your child have severe diarrhoea as your body loses more fluid, sugars and salts than normal;
- if you or your child have diarrhoea that lasts for more than 48 hours;
- if you or your child have acquired immunodeficiency syndrome (AIDS) and your stomach becomes swollen, stop taking IMODIUM® MELT TABLETS immediately and contact your doctor;
- if you or your child suffer from any liver disease;
- if you have a history of substance abuse.

Children and adolescents

IMODIUM® MELT TABLETS is contraindicated for use in children under the age of 6 years.

Other medicines and IMODIUM® MELT TABLETS

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you or your child are currently using:

- quinidine (used to treat malaria);
- ritonavir (used to treat HIV/AIDS);
- itraconazole or ketoconazole (used to treat fungal infections);
- gemfibrozil (used to treat cholesterol (high levels of fat in your blood));
- desmopressin (used to control increased thirst and too much urination);
- any other medicines used to treat diarrhoea.

IMODIUM® MELT TABLETS with food, drink and alcohol

See section 3.

This amendment: Response to Clinical Recommendation.

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Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking IMODIUM® MELT TABLETS.

The safety of IMODIUM® MELT TABLETS during pregnancy has not been established. Small amounts of IMODIUM® MELT TABLETS is excreted in breast milk.

Do not use IMODIUM® MELT TABLETS if you are pregnant or breastfeeding your baby.

Driving and using machines

You may experience tiredness, dizziness or drowsiness if you suffer from diarrhoea and you are taking IMODIUM® MELT TABLETS. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how IMODIUM® MELT TABLETS affects you.

IMODIUM® MELT TABLETS contains aspartame

Aspartame is a source of phenylalanine. It may be harmful if you or your child have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take IMODIUM® MELT TABLETS

Do not share medicines with any other person.

IMODIUM® MELT TABLETS is contraindicated in children under the age of 6 years.

Short-term diarrhoea:

Adults:

The usual dose is 2 tablets as an initial dose, followed by 1 tablet after each subsequent loose stool.

This amendment: Response to Clinical Recommendation.

Date of original submission: 12 December 2016

Children (6 – 12 years):

The usual dose is 1 tablet as an initial dose followed by 1 tablet after each subsequent loose stool.

Do not exceed the following maximum daily dosages:

WEIGHT IN KILOGRAMS (kg)	MAXIMUM DAILY DOSE
from 14 kg	2 tablets (4 mg)
from 20 kg	3 tablets (6 mg)
from 27 kg	4 tablets (8 mg)
from 34 kg	5 tablets (10 mg)
from 40 kg	6 tablets (12 mg)
from 47 kg	7 tablets (14 mg)
from 54 kg	8 tablets (16 mg)

Always take IMODIUM® MELT TABLETS 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.

It is important that you stop taking IMODIUM® MELT TABLETS as soon as your or your child's diarrhoea is under control.

Do not take for attacks that last longer than 48 hours. If your diarrhoea does not get better, you must contact your doctor.

Long-lasting diarrhoea (as per consultation with your doctor)

Adults:

The usual dose is 2 tablets daily.

Children (older than 6 years):

This amendment: Response to Clinical Recommendation.

Date of original submission: 12 December 2016

The usual dose is 1 tablet daily.

Instructions for use/handling:

To take the tablets out of the blister:

- pull the edge of the foil,
- tear the foil completely off,
- press out the tablet,
- remove the tablet.



Since the fast-dissolving tablets are fragile, the tablets should not be pushed through the blister as this would damage them.

The IMODIUM® MELT TABLETS tablet should be placed on the tongue. The orodispersible tablet will dissolve and is to be swallowed with saliva. No fluid intake is needed.

If you have the impression that the effect of IMODIUM® MELT TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more IMODIUM® MELT TABLETS than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining IMODIUM® MELT TABLETS with you so the doctor will know what you have taken.

This amendment: Response to Clinical Recommendation.

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If you forget to take IMODIUM® MELT TABLETS

You should only take IMODIUM® MELT TABLETS as you need it. If you forget to take a dose, take your next dose after your next loose stool. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

IMODIUM® MELT TABLETS can have side effects.

Not all side effects reported for IMODIUM® MELT TABLETS are included in this leaflet. Should your or your child's general health worsen or if you or your child experience any untoward effects while taking IMODIUM® MELT TABLETS, please consult your health care provider for advice.

If any of the following happens, stop taking or giving IMODIUM® MELT TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you or your child may have had a serious allergic reaction to IMODIUM® MELT TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Side effects occurring less frequently:

- lack of bowel movements causing severe constipation;
- severe stomach pain or swelling;

This amendment: Response to Clinical Recommendation.

Date of original submission: 12 December 2016

- severe, painful skin rash causing blistering or peeling of the skin, also known as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiform;
- difficulty urinating.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- headache;
- dizziness;
- constipation, dry mouth, flatulence (excessive wind), cramping or pain of your stomach area, nausea (feeling sick), vomiting (being sick), colic.

Side effects occurring less frequently:

- swelling or discomfort of your stomach area, indigestion;
- drowsiness;
- abnormal coordination, stiffness (difficulty moving);
- reduced level of consciousness or loss of consciousness (passing out, feeling faint or less alert);
- constriction of your pupils;
- tiredness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to

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SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under

SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of IMODIUM® MELT TABLETS.

For further information, please contact the Johnson and Johnson call centre on 0860 410032 (landline).

5. How to store IMODIUM® MELT TABLETS

- Store at or below 25 °C.
- Protect from moisture.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IMODIUM® MELT TABLETS contains

Each tablet contains 2 mg loperamide hydrochloride.

The other ingredients are aspartame (E951), gelatine, mannitol (E421), mint flavour and sodium hydrogen carbonate.

What IMODIUM® MELT TABLETS looks like and contents of the pack

White to off-white, circular, freeze-dried tablets.

Carton containing one aluminium blister with 6 or 10 tablets.

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Holder of certificate of registration

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

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Access to the corresponding Professional Information

The latest electronic Professional Information may be found at the SAHPRA website:

<https://www.sahpra.org.za/pi-pil-repository/>.

Alternatively, you may directly contact Johnson & Johnson (Pty) Ltd.:

Consumer Contact Centre:

0860 410032 (South Africa Only)

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