Pharmacode

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addiction is observed with opioids
have a history of drug abuse;

liver
- if you suffer from

AIDS and your

Talk to your doctor or pharmacist

Loperamide tablets.

or pharmacist before taking

Do not use this medicine if any of

child under 9 years old.

acute dysentery
constipated
- if you are

severe diarrhoea
- if you are

- If you get any side effects, talk
to your doctor or pharmacist.

- If you have any further

Keep this leaflet. You may need

Read all of this leaflet carefully

1. What Loperamide Tablet

5. How to store

3. How to use

4. Possible side effects

6. Contents of the pack and other

1. What Loperamide Tablet is and What it is used for

- Loperamide hydrochloride is the active ingredient of Loperamide Tablets. The tablets are available in

one strength. Loperamide is one of a group of medicines called "antidiarrhoeals" which are used
to treat diarrhoea.

- Loperamide 2 mg tablets are used to
treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 9 years and over and

and less frequent.

2. What you need to know before you use Loperamide Tablets

- Do not use Loperamide Tablets

- you are allergic to loperamide hydrochloride or any of the other ingredients of this medicine (listed in section 6).

- if you have severe diarrhoea after taking antibiotics

- if you have a flare up of an

inflammatory bowel condition like ulcerative colitis

- if you are constipated or your

stomach appears swollen

(particularly in children with

severe dehydration)

- if you have acute dysentery,

the symptoms of which may include

blood in your stools and a high

temperature.

Do not give this medicine to a child under 9 years old.

Do not use this medicine if any of
the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking
Loperamide tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Loperamide Tablets

- if you have AIDS and your

stomach becomes swollen, stop
taking the tablets immediately and contact your doctor.

- if you suffer from liver

problems

- if you have severe diarrhoea

as your body loses more fluid, sugars and salts than normal.

- if you have diarrhoea that lasts

for more than 48 hours.

If you are unsure about any of the

medicines you are taking, show the

bottle or pack to your pharmacist.

Consult a doctor before use if you

have a history of drug abuse;

loperamide is an opioid and

addiction is observed with opioids as a class.

Special warnings:

- Loperamide only treats the

symptoms of diarrhoea. When you have diarrhoea, your body

can lose large amounts of fluids and

sodium. You will need to

replace the fluid by drinking

more fluid than usual. This

is especially important for

children. Ask your pharmacist

about special powders (known as

oral rehydration therapy) which

replace fluids and salts lost
during diarrhoea. The prevention of

fluid depletion (dehydration) is

of particular importance in

infants, children and frail and

elderly people with acute diarrhoea.

- 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) have been

reported in patients who have taken too much loperamide, the active ingredient in Loperamide Tablet.

- Other medicines and Loperamide Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained

without a prescription. In particular, tell your doctor or pharmacist if you are taking any of the following:

- ritonavir (used to treat HIV)

- quinidine (used to treat abnormal

heart rhythms or malaria)

- itraconazole, ketoconazole (used
to treat fungal infections)

- gentamicin (used to reduce levels of cholesterol)

- oral depomedrol (used to treat excessive

arthritis)

- other drugs that slow down or

speed up movement in the gut

- Pregnancy and breast-feeding

If you are pregnant or breast-feeding,

you should check with your doctor or

pharmacist if you are not sure.

- If you have any side effects, talk
to your doctor or pharmacist.

- If you get any side effects, talk
to your doctor or pharmacist.

- If you have any further

questions, ask your doctor or

pharmacist.
Children aged under 9 years old: This medicine should not be given to children under 9 years old. Other pharmaceutical forms/strengths (e.g. syrup) are available for children aged 4 years and over.

If your symptoms are not getting better within 2 days of taking your first dose of this medicine, you should see your doctor again, who may want to examine you to further check on the cause of the diarrhoea.

Long-lasting (chronic) diarrhoea

Adults only: - Your doctor will tell you how much Loperamide tablets to take.

- The initial dose will probably be between two and four tablets per day taken in divided doses, but will depend on each individual’s needs. When your doctor is satisfied that you are receiving the daily dose that best suits you, he or she will then probably suggest that you take your tablets twice a day.

- Never take more than 8 tablets in any 24 hour period.

If you take more Loperamide Tablets than you should

If you have taken too many Loperamide tablets, immediately contact a doctor or hospital for advice.

Symptoms may include: increased heart rate, irregular heartbeat, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating, or weak breathing, reduction in size of the pupils in the eye (miosis), constipation and a condition where the bowel does not work properly (ileus). Children react more strongly to large amounts of loperamide than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

If you forget to take Loperamide Tablets

- You should only take this medicine as required following the dosage instructions above carefully.
- If you forget to take a dose, take a dose after the next loose stool (bowel movement).
- 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.

Stop using Loperamide tablets and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment:

- Sudden swelling of the face lips, or throat. Hives (also known as nettle rash or urticaria).
- Severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction
- Blistering of your skin, mouth, eyes or genitals
- Stomach pain or severe swollen stomach
- Severe constipation
- Loss of consciousness or reduced level of consciousness (feeling faint)

Tell your doctor if you notice any of the following side effects while using Loperamide tablets:

Common side effects (may affect up to 1 in 10 people)

- Headache
- Feeling sick (nausea)
- Constipation
- Wind

Uncommon side effects (may affect up to 1 in 100 people)

- Feeling sleepy or drowsy
- Dry mouth
- Being sick (vomiting), indigestion (dyspepsia)
- Rash
- Abdominal pain or discomfort
- Feeling dizzy

Rare side effects (affects fewer than 1 in 1000 people)

- Tiny pupils
- Itchy skin
- Difficulty passing water
- Feeling tired
- Problems with co-ordination
- Unusually stiff muscles causing poor control of movement
- Burning, tingling mouth (glossodynia)

Some of the listed side effects may be due to the diarrhoea, such as discomfort around the middle, feeling sick or being sick, dry mouth, feeling tired, drowsy or dizzy and wind.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Loperamide Tablets

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 label or carton after “EXP.” The expiry date refers to the last day of that month.

Store in the original package. If the tablets become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

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 Loperamide Tablets contain

- The active substance is loperamide hydrochloride. Each tablet contains 2 mg loperamide hydrochloride.
- The other ingredients are maize starch, lactose monohydrate, povidone (K-30), Brilliant Blue FCF (E133), quinoline yellow (E104), magnesium stearate, talc, colloidal anhydrous silica and sodium starch glycollate and purified water.

What Loperamide Tablets looks like and contents of the pack

Loperamide Tablets are light green coloured capsule shaped, biscones uncoated tablets with ‘2’ debossed on one side and scoreline on other side.

The aero line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Loperamide is presented in a blister pack of 12 or 50 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder: Cipla (EU) Limited, Dixcart House, Addlestone Road, Bournemouth Park, Addlestone, Surrey, KT15 2LE, United Kingdom

Manufacturers: Cipla (EU) Limited, Dixcart House, Addlestone Road, Bournemouth Park, Addlestone, Surrey, KT15 2LE, United Kingdom

This leaflet was last revised in August 2020
PACKAGING DEVELOPMENT

Product Name: Loperamide 2mg POM - 0111 Cipla (EU) Own Ltd (safety variation)

Material No.: 21083966
Item: Leaflet
Version: 01
Date: 18/09/2020
Co-ordinator: Shweta
Artist: Avadhoot
Software: Illustrator CC

Fonts: ------
Colours: BLUE WOOL TEST VALUE 5-8 (LIGHT FASTENING DATA)

Varnish: ---
Material: 54 GSM Maplitho Paper
Actual Size: 130 x 470 mm
Grain Direction: Parallel to length

Path: Avadhoot \ F:\Export\EUROPE\DTM\Loperamide Tablets \ 21083966 Loperamide 2mg POM - 0111 Cipla (EU) Own Ltd (safety variation) PIL UK.ai
INK: Oil based Ink from DIC OR MICRO
Screen: # __

Reference / Supersedes: 21074238
Links: NA
Pharmacode: Artwork Print Size: Design: Unfolded
Size after folding: ---

Any deviation must be brought to the notice of packaging development co-ordinator immediately.
For any clarification, please contact packaging development co-ordinator immediately.
The printer should verify the e-proof against the approved artwork before submitting for approval and the e-proof should have printer details.

BRS Cipla EU

BRS-D-29-00111