DIATROL TABLET®

Loperamide Hydrochloride (2mg)

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What Diatrol Tablet is used for

Diatrol Tablet is used for control and symptomatic relief of acute, non specific diarrhea and chronic diarrhea associated with inflamantory bowel disease. In people with ileostomy(surgical procedure in which small intestine is diverted through an opening in the abdomen to move waste out of the body), it can be used to reduce the number and volume and harden the stools.

How Diatrol Tablet Works

The active ingredient in the medicine is loperamide prolongs the transit time of the intestinal contents. It reduces the daily faecal volume, increases the viscosity and bulk density, and diminishes the loss of fluid and electrolytes by both increasing the intestinal absorption and decreasing intestinal secretions.

Before you use Diatrol Tablet

- When you must not use it

Do not take Diatrol Tablet:

- If you have known hypersensitivity to Loperamide or other ingredients of this product.
- If you have colon constipation.
- If you have acute inflammation of the colon which can be associated with broad spectrum antibiotics.
- If you have acute dysentery which is characterized by blood in stools and high fever.
- If children under 6 years of age.
- If you are breastfeeding

- Before you start to use it

You should check with your doctor:-

- If you are or think you may be pregnant
- If you are planning to become pregnant
- If you have diabetes

- If you are having acute diarrhea associated with bacteria
- If you are depleting water and salts
- If you have liver failure
- If you are having acute diarrhea and your condition does not improve after 2 days

Diatrol Tablet should only be used during pregnancy when clearly needed.

- Taking Other Medicines

There are no drug interaction have been reported except for drugs similar pharmacological properties. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription.

How to use Diatrol Tablet

- How much to use

You should take Diatrol Tablet exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

For adult dosage:

In acute diarrhoea, the recommended initial dose of 2 tablets (4mg) followed by 1 tablet (2mg) after each unformed stool. Daily dosage should not exceed 8 tablets (16mg).

In chronic diarrhoea, the recommended initial dosage of loperamide is 2 tablets (4mg) followed by 1 tablet (2mg) after each unformed stool until diarrhea is controlled, after which the dosage should be reduced to meet individual requirements. When the optimal daily dosage had thus been established, this amount should then be taken as a single dose or in divided doses.

- When to use it

Refer to your doctor or pharmacist.

- How long to use it

It is important to take Diatrol Tablet as long as your doctor prescribes.

- If you forget to use it

Do not take extra dose to make up for a missed dose. Just take your next dose at usual the time.

- If you use too much (overdose)

If you take too much of the medication by mistake, contact your doctor immediately or seek medical attention. Over dosage of loperamide may result in constipation, central nervous system depression and gastrointestinal irritation.

While you are using it

- Things you must do

Take Diatrol Tablet exactly the way as prescribed.

- Things you must not do

Do not share your medicine with others even if they have the same condition as you.

- Things to be careful of

If you experience any side effects, consult your doctor or pharmacist for advise.

Side Effects

Like all medicines, Diatrol Tablet can cause side effects, although not everybody gets them. Adverse experiences recorded during clinical studies with loperamide HCl were generally of a minor and self-limiting nature. They were more commonly observed during the treatment of chronic diarrhoea.

The following complaints have been reported such as abdominal pain, constipation, drowsiness or dizziness, dry mouth, nausea and vomiting, tiredness, hypersensitivity reactions (including skin rash).

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting).

Storage and Disposal of Diatrol Tablet

- Storage

Store at temperature 25°C. Protect from light.

- Disposal

If you have any unwanted tablets, do not put them in waste water or household rubbish. Ask your pharmacist how to dispose of the tablets. These measures will help to protect the environment.

Product Description

- What it looks like

Round and convex tablet with light blue coloured, plain tablet with 'SW' debossed on one side.

- <u>Ingredients</u>Active Ingredient
- Loperamide Hydrochloride
- Inactive Ingredients
- Sodium Starch
- Lactose
- Corn Starch
- Lake Blue # 2
- Magnesium Stearate

-MAL number MAL20002519AZ

Manufacturer

Sunward Pharmaceutical Sdn. Bhd. 9,11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd. 9,11 & 17 Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

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