SUN-DIANOX TABLET

Diphenoxylate Hydrochloride/Atropine Sulphate (2.5mg/0.025mg)

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What Sun-Dianox Tablet is used for

It is used effective as additional therapy in the management of acute and chronic diarrhea.

How Sun-Dianox Tablet works

The active ingredients in this medicine are Diphenoxylate Hydrochloride and Atropine Sulphate. Diphenoxylate Hydrochloride has a direct effect which helps to decrease the number and frequency of bowel movements. It works by slowing the movement of the intestines. Atropine a naturally occurring alkaloid is an anticholinergic agent. It acts by reducing the motor activity in the stomach, small and large intestines to treat diarrhoea.

Before you use Sun-Dianox Tablet

- When you must not use it

Do not use Sun-Dianox Tablet if:-

- you are hypensitive to diphenoxylate or atropine or other ingredients of this product.
- you have jaundice.
- you have diarrhea associated with the use of certain antibiotics or bacterial infection.
- you have intestinal obstruction, ulcers and inflammation in the digestive tract.
- your activities requiring mental alertness, such as driving or operating dangerous machinery as it may produce drowsiness or dizziness.

- Before you start to use it

You should check with your doctor if you have the following :-

- down's syndrome
- breast feeding
- pregnant
- liver disease

Appropriate fluid and electrolyte therapy should be taken to prevent dehydration due to diarrhoea. Oral rehydration therapy including oral rehydration salts remains the most effective treatment for dehydration due to diarrhoea. The intake of as much of these fluids as possible is therefore imperative.

Sun-Dianox should be used during pregnancy only if the anticipated benefit justifies the potential risk to the fetus.

- Taking other medicines

There are a few medicines which may not take with Sun-Dianox Tablet. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. The concurrent use of diphenoxylate HCL with monoamine oxidase (MAO) inhibitors. Diphenoxylate hydrochloride may potentiate the action of sedative, tranquilizers and alcohol.

How to use Sun-Dianox Tablet

- How much to use

Oral administration.

Adults

The recommended initial dosage is 5mg (two tablets) four times daily. Most people will require this dosage until initial control has been achieved, after which the dosage may be reduced to meet individual requirements. Control may often be maintained with as little as 5mg (two tablets) daily.

Clinical improvement of acute diarrhoea is usually observed within 48 hours. If clinical improvement of chronic diarrhoea after treatment with a maximum daily dose of 20mg of diphenoxylate hydrochloride is not observed within 10 days, symptoms are unlikely to be controlled by further administration.

Children

Sun-Dianox is not recommended in children under 6 years of age and should be used with special caution in young children. The recommended initial total daily dosage for children is 0.3 to 0.4mg/kg, administered in four divided doses. The following table provides an approximate initial daily dosage recommendation for children.

Age	Approximate Body Weight	Dosage
6 - 8 years	20 -27 kg	1 tablet, 3 times daily
8 - 12 years	27 – 36 kg	1 tablet, 4 times daily
12 years and over		2 tablets, 3-4 times daily (adult dosage)

- When to use it

Use Sun-Dianox Tablet when needed and according to your doctor's prescription.

- How long to use it

It is important to take Sun-Dianox 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 time.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Initial signs of over dosage may include dryness of the skin and mucous membranes, dilation of pupil, restlessness, flushing, hyperthermia (abnormal high body temperature), and abnormal rapid heart rate followed by lethargy or coma, low muscle tone reflexes, involuntary movement of eyes and respiratory depression.

While you are using it

- Things you must do

Take Sun-Dianox tablet exactly the way as prescribed.

- Things you must not do

Do not share your medicines with others even if they have same diagnosis as you.

- Things to be careful of

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

Side effects

Like all medicines, Sun-Dianox Tablet can cause side effects, although not everybody gets them. At therapeutic doses, the following have been reported.

Nervous System: Numbness on hand or foot, happiness or excitement, depression, fatigue/ tiredness, confusion, sedation/drowsiness, dizziness, restlessness and headache.

Allergic: Anaphylaxis, swelling of the skin dermis, hives, swelling of the gums and itching.

Gastrointestinal: Bowel inflammation, paralysis of the intestinal muscles, pancreases inflammation, vomiting, nausea, eating disorder and abdominal discomfort.

Atropine Sulphate effects are hyperthermia, rapid heartbeat, urinary retention, flushing, dryness of the skin and mucous membranes. These effects may occur, especially in children.

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication.

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 Sun-Dianox Tablet

- Storage
Store at or below 30 °C. Protect from light.

- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like
Round, white, deep convex, plain tablet with "SW" debossed on one side.

- Ingredient(s)
- Active Ingredient
Diphenoxylate Hydrochloride 2.5mg
Atropine Sulphate 0.025mg

- Inactive Ingredients
- Lactose
- Maize Starch
- Magnesium stearate

- MAL number
MAL19991906AZ

Manufacturer
Sunward Pharmaceutical Sdn. Bhd.
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Perindustrian Tampoi Indah, 81200
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Product Registration Holder
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