

ZORALIX ELIXIR

Promethazine hydrochloride (5mg/5ml, 10mg/5ml)

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This leaflet answers some common questions about ZORALIX ELIXIR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What ZORALIX ELIXIR is used for?

ZORALIX ELIXIR is an antihistamine used to treat a number of conditions:

- Allergic conditions
- Motion sickness
- Nausea & vomiting
- Hypnosis

How ZORALIX ELIXIR works?

ZORALIX ELIXIR contains Promethazine hydrochloride as an active ingredient.

Promethazine hydrochloride is an antihistamine which helps to reduce allergic symptoms by preventing the effects of a substance called histamine.

Histamine is produced by the body in response to foreign substances that the body is allergic to.

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use ZORALIX ELIXIR

When you must not take it

Do not take ZORALIX ELIXIR if you are hypersensitive to:

- Any medicine containing promethazine hydrochloride
- Other anti-histamines of similar chemical of structure
- Any of the ingredients listed at the end of this leaflet.

Before you start to use it

Take special care with ZORALIX ELIXIR:

- Do not use for children under two years of age, due to the potential for fatal respiratory depression.

Pregnancy and breast feeding:

Ask your doctor or pharmacist for advice before taking any medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other

medicines, including medicines obtained without a prescription.

Some medicines and ZORALIX ELIXIR may interfere with each other. These include:

- anti-cholinergic agent, tricyclic anti-depressant, sedative or hypnotic
- other antihistamines
- alcohol

How to use ZORALIX ELIXIR

How much to use

Allergic Conditions

Zoralix Elixir 5mg/5ml

Dosage	Single Dose At Night	2 - 3 Times A Day Dose
2 - 5 years	5 - 15 ml	5 ml
6 - 12 years	10 - 25 ml	10 ml

Zoralix Elixir 10mg/5ml

Dosage	Single Dose At Night	2 - 3 Times A Day Dose
2 - 5 years	2.5 – 7.5 ml	2.5 ml
6 - 12 years	5 – 12.5 ml	5 ml

Hypnosis

For short term use on the advice of a pharmacist or doctor.

Zoralix Elixir 5mg/5ml

Dosage	Single Dose At Night
2 - 5 years	5 - 15 ml
6 - 12 years	10 - 25 ml

Zoralix Elixir 10mg/5ml

Dosage	Single Dose At Night
2 - 5 years	2.5 – 7.5 ml
6 - 12 years	5 – 12.5 ml

Motion Sickness

Zoralix Elixir 5mg/5ml

Dosage	
2 - 5 years	5 ml
6 -12 years	10 ml

Zoralix Elixir 10mg/5ml

Dosage	
2 - 5 years	2.5 ml
6 -12 years	5 ml

Nausea and Vomiting

Zoralix Elixir 5mg/5ml

Dosage	
2 - 5 years	5 ml every 4 to 6 hours to a maximum daily dose of 15 ml.
6 -12 years	10 ml every 4 to 6 hours to a maximum daily dose of 25 ml.

Zoralix Elixir 10mg/5ml

Dosage	
2 - 5 years	2.5 ml every 4 to 6 hours to a maximum daily dose of 7.5 ml.
6 -12 years	5 ml every 4 to 6 hours to a maximum daily dose of 12.5 ml.

When to use it

Take the medicine after meal.

How long to use it

Do not exceed the recommended dosage and do not use for longer than 10 days in a row.

If you forget to use it

Take the missed dose as soon as you remember.

If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time.

Do not take a double dose to make up for the one you have missed.

If you use too much (overdose)

If you accidentally take too much of ZORALIX ELIXIR, overdose

may vary from central nervous system depression to stimulation. Atropine like signs and symptoms such as dry mouth, fixed dilated pupils, flushing and gastrointestinal symptoms may also occur.

While you are using ZORALIX ELIXIR

Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking ZORALIX ELIXIR.

Things you must not do

Do not consume any food or beverages or carry out any activities which are restricted by doctors while taking ZORALIX ELIXIR.

Things to be careful of

During the first days of treatment with ZORALIX ELIXIR reactions may be impaired. Do not to take charge of vehicles or machinery until the effect of ZORALIX ELIXIR treatment on the individual is known.

Side effects

ZORALIX ELIXIR may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away.

- dry mouth
- stomach upset
- loss of appetite
- nausea or vomiting
- diarrhoea or constipation
- tiredness or sleepiness
- low blood pressure
- dizziness
- blurred vision
- muscular weakness
- in-coordination
- jaundice - yellow tinge to skin or eyes
- tinnitus - buzzing, hissing, ringing or other persistent noise in the ears

- irritability

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Storage and Disposal of ZORALIX ELIXIR

Storage

Store below 30°C. Keep out of the reach of children. Protect from strong light. Keep container well closed.

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

Zoralix Elixir 5mg/5ml is clear orange syrup liquid with banana flavour and odour

Zoralix Elixir 10mg/5ml is clear dark orange coloured liquid with slight banana and vanilla flavour and sweet taste.

Ingredients

Active ingredients:
Promethazine Hydrochloride

Inactive ingredients:
Sodium Benzoate, Sunset Yellow, Quinoline Yellow, Sodium Citrate, Vanilla Flavour, Banana Flavour 103, Citric Acid Anhydrous, Propylene Glycol, Propyl Gallate, Sodium Edetate, Sucrose and Purified Water.

MAL number:

Zoralix Elixir 5mg/5ml:
MAL19861128A
Zoralix Elixir 10mg/5ml:
MAL19890243A

Manufacturer :

HOE Pharmaceuticals Sdn Bhd
Lot 10, Jalan Sultan Mohamed 6,
Bandar Baru Suleiman,
42000 Port Klang, Selangor,
MALAYSIA.

Product Registration Holder:

HOE Pharmaceuticals Sdn Bhd
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Date of Revision :

19/05/2014