PACKAGE LEAFLET: INFORMATION FOR THE USER

Dibondrin liquid

Active substance: diphenhydramine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What *Dibondrin liquid* is and what it is used for
2. What you need to know before you take *Dibondrin liquid*
3. How to take *Dibondrin liquid*
4. Possible side effects
5. How to store *Dibondrin liquid*
6. Contents of the pack and other information

1. What *Dibondrin Liquid* is and what it is used for

Diphenhydramine hydrochloride, the active substance, is a known, tried-and-tested H_1 antihistamine. In addition to anti-allergic and antipruritic (anti-itching) effects, diphenhydramine also has marked sedative and sleep-inducing properties.

Use as an antihistamine and antiallergic agent
For the supportive treatment of allergic reactions, such as allergies to pollen, food and medicines, allergic rhinitis, hives, itching, inflammatory skin reactions, contact dermatitis, itchy rash, swelling of the mucous membranes and hypersensitivity reactions.

Use as a hypnotic (sleep-inducing drug)
Dibondrin is a sleep-inducing drug used for sleep disorders (problems in falling and staying asleep) due to various factors (restlessness, nervousness, exhaustion). *Dibondrin* makes it easier to fall asleep and prolongs the duration of sleep, particularly in sleep disorders accompanied by itching or allergic symptoms.

In general, the effect sets in 15 to 30 minutes after taking Dibondrin liquid and lasts for 4 to 6 hours.

2. What you need to know before you take *Dibondrin Liquid*

Do not take *Dibondrin liquid*
- if you are allergic to diphenhydramine hydrochloride, other antihistamines of a similar chemical structure or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding
- in the first 3 months of pregnancy
- if you are having an acute asthma attack
- if you suffer from narrow-angle glaucoma
- if you have an adrenal tumour (phaeochromocytoma)

- if you have a seizure disorder (e.g. eclampsia, epilepsy)
- together with alcohol
- together with medicines that also prolong the QT time (contraction of the heart's ventricular muscle), e.g. class Ia and III antiarrhythmic agents)
- together with other medicines also containing diphenhydramine or other H_1 antihistamines
- together with MAO inhibitors (antidepressants)

Warnings and precautions
Talk to your doctor or pharmacist before taking *Dibondrin*.

Dibondrin may only be used with caution if
- you suffer from chronic breathing problems and asthma,
- you have a stomach or intestinal ulcer or pyloric stenosis (narrowing of the stomach outlet),
- you have an enlarged prostate and urinary outflow problems,
- you have heart dysfunction, heart rhythm disorders or tachycardia (racing heart),
- you have an overactive thyroid.
- If your kidney or liver function is impaired, the dose should be reduced.

Dibondrin reduces alertness; states of agitation may also occur in children.

In allergy tests, *Dibondrin* can lead to false-negative results. *Dibondrin* should therefore not be taken for at least 3 days before such tests.

Dibondrin should not be administered after midnight if full alertness is required on the following morning.

Other medicines and *Dibondrin liquid*
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Dibondrin liquid must not be taken at the same time as medicines that also contain diphenhydramine or other H_1 antihistamines (certain antiallergic agents), including those applied topically, as this may enhance the effect of both medicines in an unpredictable manner.

Dibondrin liquid must not be taken together with alcohol.

Administration of medicines that also prolong the QT time (contraction of the heart's ventricular muscle), such as class Ia and III antiarrhythmic agents, must be avoided.

Dibondrin must not be used at the same time as MAO (monoamine oxidase) inhibitors (certain medicines for Parkinson's disease and depression), as these may enhance the effect.

If used at the same time as medicines that suppress the central nervous system (anaesthetics, sedatives, sleep aids, painkillers, antidepressants and anti-epileptic agents), the effect may be enhanced.

Dibondrin enhances the effect of adrenaline, noradrenaline and other sympathomimetic agents.

If given at the same time as other substances with anticholinergic effects, such as atropine, biperiden and tricyclic antidepressants, the effect may be enhanced.

The use of medicines for high blood pressure that act on the CNS (such as guanabenz, clonidine, methyldopa) can, together with Dibondrin, lead to increased tiredness.

***Dibondrin liquid* with food and drink**
Dibondrin liquid must not be taken together with alcohol, as it can enhance the effect in an unpredictable manner.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Dibondrin liquid must not be used in the first 3 months of pregnancy, as there is an increased risk of cleft palate formation. During the remainder of pregnancy, *Dibondrin liquid* should be used only after a careful benefit/risk assessment and after the individual dose has been established by the doctor. Repeated use during pregnancy is not recommended.

During breast-feeding, *Dibondrin liquid* must not be used.

Driving and using machines


Warning: This medicine can impair responsiveness and the ability to drive.

Do not drive or use any tools or machines because this medicine can affect responsiveness. This applies particularly in combination with alcohol.

When taken after midnight, impaired responsiveness (a hangover) can be expected on the morning after.

***Dibondrin liquid* contains sorbitol, aspartame and sodium methylhydroxybenzoate**

This medicine contains sorbitol. If you have been told that you have an intolerance to some sugars, please consult your doctor before taking *Dibondrin liquid*.

Contains a source of phenylalanine and may be harmful if you have phenylketonuria.

Contains sodium methylhydroxybenzoate, which may cause allergic reactions (possibly delayed).

3. How to take *Dibondrin liquid*

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The pack contains a dosing syringe graduated at 1 – 10 mL for easier dosing.
Please use the dosing syringe to measure the Dibondrin liquid dose.
To remove Dibondrin liquid, insert the dosing syringe into the bottle opening, withdraw the appropriate dose amount and then swallow/administer from the dosing syringe.

Unless otherwise prescribed, the usual dose is:

For use as an antihistamine, antiallergic agent
Adults and adolescents aged 12 years and older take 15 – 45 mL Dibondrin liquid 2 to 3 times daily.

Children take *Dibondrin liquid* according to the following dosing regimen:

Age	Daily dose	
up to 2 years	twice	2.5 mL daily
3 – 5 years	2 – 3 times	5 mL daily
6 – 9 years	3 – 4 times	5 mL daily
aged 10 years and older	3 times	10 mL daily

For use as a hypnotic (sleep-inducing drug), sedative

Adults and adolescents aged 12 years and *older* take 15 – 30 mL (45 mL maximum) as a single dose 15 to 30 minutes before bedtime

Children take Dibondrin liquid according to the following dosing regimen:

Age	Single dose of
up to 2 years	2.5 mL
3 – 5 years	5 mL
6 – 9 years	7.5 mL
aged 10 years and older	10 mL

Adults must take no more than 45 mL Dibondrin liquid per single dose.

In *old* or *debilitated patients* and *patients with severe kidney or liver damage*, the dosage should be carefully adjusted to the clinical picture (see below).

Dosage in elderly patients:
Patients over 60 years of age should closely follow the dosage prescribed by the doctor. A lower starting dose may be recommended, as side effects (dizziness, sedation, drop in blood pressure) can increasingly occur.

Dosage in *senium (advanced old age*):
They should strictly observe the dosage prescribed by their doctor. Where appropriate, a lower starting dose may be recommended, as side effects (dizziness, sedation, and decrease in blood pressure) may increasingly occur.

Dosage in cases of *renal insufficiency*:
An increase in the dosing interval to 6-12 hours for a GFR of 10-50 mL/min) or 12-18 hours for a GFR of <10 mL/min) is recommended.

In prolonged sleeping disorders, the need for treatment should be reviewed after two weeks of taking this medicine every day.

If you take more *Dibondrin liquid* than you should
An overdose with diphenhydramine hydrochloride can be dangerous; this applies particularly to children.

Should an overdose occur, it will be characterised by central symptoms such as restlessness, heightened muscle reflexes, psychosis, unconsciousness, shortness of breath or even cardiovascular arrest. Other symptoms are pupil dilation, racing heart, fever, hot and red skin or dry mucous membranes and symptoms similar to atropine poisoning.

In this event, please contact a doctor immediately.

Notes for healthcare professionals
You will find information on treating an overdose at the end of this package leaflet.

If you forget to take *Dibondrin liquid*
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.

Side effects may occur at the following frequencies:
-*Very common (≥ 1/10)*
-*Common (≥ 1/100 to <1/10)*
-*Uncommon (≥ 1/1,000 to < 1/100)*
-*Rare (≥ 1/10,000 to < 1/1,000)*
-*Very rare (< 1/10,000)*
-*Not known (cannot be estimated from the available data)*

The following side effects may occur:

Blood and lymphatic system disorders
Very rare: blood count changes (a lack of certain blood cells)

Nervous system disorders
Very common: tiredness. If used as a sleep aid, this is the main intended effect; when used as an antihistamine and antiallergic agent, this is a side effect.
Uncommon: dizziness, drowsiness, headache, impaired concentration and coordination, muscle weakness. When administered at night, a morning hangover (impaired responsiveness) can be expected, depending on the timing and dosage.
Very rare, especially in children: paradoxical reactions in the form of central excitation, such as restlessness, irritability, anxiety and tremor.

Eye disorders
Uncommon: visual disturbances, increased inner eye pressure.

Cardiac and vascular disorders
Uncommon: circulation problems
Rare: racing heart

Respiratory, thoracic and mediastinal disorders
Uncommon: thickening of bronchial mucus, breast tenderness

Gastrointestinal disorders; renal and urinary disorders
Uncommon: gastrointestinal complaints (nausea, vomiting, diarrhoea, constipation, reflux) and impaired urine output.

Hepatobiliary disorders
Rare: liver dysfunction (cholestatic jaundice) has been observed in some cases during treatment with antihistamines.

Skin and subcutaneous tissue disorders
Uncommon: dryness of the mouth, nose and throat
Rare: allergic skin reactions, inflammatory skin reactions, contact dermatitis and photosensitivity of the skin (avoid direct sun exposure).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system:
Bundesamt für Sicherheit im Gesundheitswesen
(Federal Office for Safety in Health Care)
Traisengasse 5
1200 VIENNA
AUSTRIA
fax: + 43 (0)50 555 36207

website: http://www.basg.gv.at/

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dibondrin liquid

Do not store above 30°C.
Store in the original package in order to protect from light. Keep the bottle tightly closed.
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 carton/label after <*EXP*>. The expiry date refers to the last day of that month.

After opening, use within 3 months.

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 Dibondrin liquid contains
- The active substance is: diphenhydramine hydrochloride
  1 mL solution contains 2 mg diphenhydramine hydrochloride.
- The other ingredients are: sorbitol, aspartame (E951), hydroxyethylcellulose, sodium cyclamate, saccharin sodium, cherry flavouring uncoloured, citric acid monohydrate, sodium methylhydroxybenzoate (E219), purified water

What Dibondrin liquid looks like and contents of the pack
100 mL clear, colourless oral solution, flavoured, in amber glass bottles (III) plus cup with markings from 2.5-20 mL.

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MA No.: 11.361

This leaflet was last revised in 04/2014.

The following information is intended for healthcare professionals only:

Treatment of intoxication:
Intoxication in children and adults is treated in the same way.
Therapy is symptomatic. Clinical surveillance. Vasopressors can be given for hypotension and diazepam (IV) for seizures.
As an antidote, physostigmine salicylate after a physostigmine test is recommended.
Do not administer any stimulants.