PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Dibondrin - Ampoules

Active substance: diphenhydramine hydrochloride

Read all of this leaflet carefully before you start using 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 – Ampoules* are and what they are used for

Dibondrin – Ampoules are indicated in adults, adolescents and children aged 2 years and older.

This medicine is intended for intravenous and intramuscular injection in adults and children.

Use as an antihistamine and antiallergic agent
Diphenhydramine hydrochloride, the active substance of *Dibondrin – Ampoules*, is a tried-and-tested agent for the prevention and acute treatment of shock caused by allergies.
In combination with epinephrine (adrenaline), Dibondrin is an effective agent to treat anaphylactic shock.

Prevention and acute treatment of immediate-type allergies influenced by histamine, such as hives, itching, skin inflammation, angioedema (extensive skin swelling), allergic rhinitis, allergies to pollen, food and medicines, hypersensitivity reactions of the skin caused by allergic reactions and swollen mucous membranes.

Use as a sleeping aid and sedative
Dibondrin is a sleeping aid used in patients who have problems falling and staying asleep (restlessness, nervousness, exhaustion). It makes falling asleep easier and prolongs the duration of sleep in sleep disorders, which are accompanied by itching or allergic symptoms.

2. What you need to know before you use *Dibondrin – Ampoules*

Do not use *Dibondrin – Ampoules*
- if you are allergic to diphenhydramine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- during the first 3 months of pregnancy
- during breast-feeding

- in newborn infants and children under 2 years of age
- if you are having an acute asthma attack.
- if you have an adrenal tumour (phaeochromocytoma).
- if you have narrow-angle glaucoma.
- if you have a seizure disorder (e.g. epilepsy).
- if you are currently using certain medicines (e.g. for heart rhythm disorders) that prolong the QT interval (certain ECG abnormalities that your doctor will identify).

Warnings and precautions
Please talk to your doctor or pharmacist before taking *Dibondrin - Ampoules*.

Take special care using *Dibondrin - Ampoules*

- if you suffer from chronic breathing problems and asthma,
- if you have a stomach or intestinal ulcer or suffer from a narrowing of the stomach outlet,
- if you have an enlarged prostate and your urine outflow is impaired,
- if you have a heart function problem or a heart rhythm disorder,
- if you have an overactive thyroid.
- If liver and renal function is impaired, the dose should be restricted (see section "*Dosage*").

Dibondrin – Ampoules contain sodium, but less than 1 mmol (23 mg) sodium per ampoule, i.e. essentially 'sodium-free'.

24 hours before performing allergy tests, Dibondrin must be discontinued.

Other medicines and *Dibondrin – Ampoules*
Tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines.

Dibondrin – Ampoules should not be used at the same time as medicines containing diphenhydramine or other H_1-antihistamines (certain antiallergic agents), as this may mutually enhance the effect of both medicines in an unpredictable manner.

Due to possible enhanced effects on the heart (prolongation of the QT interval, i.e. ECG abnormalities that your doctor will identify), combined use of Dibondrin and medicines to treat heart rhythm disorders must be avoided.

The effects may be enhanced during combined use of medicines that suppress the central nervous system (psychotropic agents, antidepressants, sleeping aids, painkillers, anaesthetics) and alcohol.

Dibondrin must not be used at the same time as monoamine oxidase inhibitors (certain medicines for Parkinson's disease and depression), as these may enhance the effect. This also applies to the co-administration of other substances with anticholinergic effects, such as atropine, biperiden and tricyclic antidepressants. Dibondrin enhances the effect of adrenaline, noradrenaline and other sympathomimetic agents.

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

***Dibondrin – Ampoules* with food, drink and alcohol**
Concomitant intake of alcohol may 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 – Ampoules 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 – Ampoules* should be used only after a careful benefit/risk assessment by the doctor and after the individual dose has been established.
Repeated use during pregnancy is not recommended.

Dibondrin – Ampoules must not be used during breast-feeding.

Driving and using machines
⚠ Do not drive or use machines because Dibondrin causes drowsiness and impairs reaction skills. This applies particularly in combination with alcohol.

When administered after midnight, impaired reaction skills (a hangover) can be expected the following morning.

***Dibondrin – Ampoules* contain sodium**
Dibondrin – Ampoules contain sodium, but less than 1 mmol (23 mg) sodium per ampoule, i.e. essentially 'sodium-free'.

3. How to use *Dibondrin – Ampoules*

This medicine is administered only by a doctor or medically trained nursing staff.

Slow intravenous or deep intramuscular injection (IV: maximum 25 mg/min), do not mix with other solutions for injection in the same syringe.

The recommended dose is
for adults and adolescents aged 12 years and older:

Antihistamine, antiallergic agent:	1 – 2 ampoules, 3 times daily
Sleeping aid and sedative:	1 – 2 ampoules as a single dose before bedtime

for children aged 2 years and older:

Antihistamine, antiallergic agent:	1 ampoule per 18 kg body weight, 3 times daily
Sleeping aid and sedative:	½ ampoule per 18 kg body weight as a single dose before bedtime

The maximum daily dose is for:

Adults:	400 mg
Children:	300 mg

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

Dosage for elderly patients:
Possibly use a lower starting dose, as side effects (dizziness, sedation, drop in blood pressure) are more likely to occur.

Dosage for patients with impaired kidney function:
An increase in the dosing interval to 6-12 hours (GFR 10-50mL/min) or 12-18 hours (GFR <10mL/min) is recommended. There have been no clinical studies with repeated doses.

Dosage for patients with liver cirrhosis:

Delayed excretion. Safe and effective as an intravenous single dose. There have been no clinical studies with repeated doses.

Dibondrin – Ampoules are primarily used for acute treatment; there are no results available for long-term, interval-free treatment with parenteral diphenhydramine.

If you use more *Dibondrin – Ampoules* than you should
As this medicine is administered by the doctor or by medically trained nursing staff, an overdose is unlikely.
To date, no case of overdose with *Dibondrin - Ampoules* has been reported.

However, if an overdose with Dibondrin should nevertheless occur, it will be characterised by centrally controlled symptoms such as restlessness, heightened muscle reflexes, unconsciousness, shortness of breath or even cardiovascular arrest.
Other signs are pupil dilation, racing heart, fever, hot and red skin, dry mucous membranes and symptoms similar to atropine poisoning.

In this case, please contact a doctor immediately.

If you forget to use *Dibondrin – Ampoules*
Do not use a double dose to make up for a forgotten dose.

If you stop using *Dibondrin – Ampoules*
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, <1/10)
Uncommon (≥1/1,000, <1/100)
Rare (≥1/10,000, <1/1,000)
Very rare (<1/10,000)
Not known *(*cannot be estimated from the available data*)*

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

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

Nervous system disorders
Very commonly (≥1/10) tiredness occurs. This is intended when used as a sleeping aid; 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 during the night, a morning hangover (impaired reaction skills) can be expected, depending on the timing and dosage.
Very rare, especially in children: central excitation, such as restlessness, irritability, anxiety and tremor.

Eye disorders
Uncommon: visual disturbances, increased inner eye pressure

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

Gastrointestinal disorders, renal and urinary disorders
Uncommon: gastrointestinal complaints and bladder voiding problems

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

General disorders and administration site conditions
Uncommon: increased blood flow and increased sensitivity at the injection site.

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

Bundesamt für Sicherheit im Gesundheitswesen
Traisengasse 5
1200 WIEN
ÖSTERREICH
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 – Ampoules*

Do not freeze. Store in the original package in order to protect from light.

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 container after "*EXP*". The expiry date refers to the last day of that month.

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 – Ampoules* contain
- The active substance is: diphenhydramine hydrochloride
- The other ingredients are: sodium chloride, water for injections, hydrochloric acid solution for pH adjustment

What *Dibondrin – Ampoules* look like and contents of the pack
Colourless, clear solution for injection.

Pack with 5 glass ampoules (glass type I), each containing 2 mL.

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Note for the physician:
Measures in the event of overdose:
Clinical surveillance. Treatment of an overdose is symptomatic. Vasopressors can be given for hypotension and diazepam or thiopental for seizures. As an antidote, physostigmine salicylate after a physostigmine test is recommended.
Do not administer any stimulants.