



MakoAche®

10 mg/ml, solution for infusion Paracetamol 1 g - 100 ml Vial

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

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1. What MakoAche 10 mg/ml, solution for infusion is and what it is used for

This medicine is an analgesic (it relieves pain) and an antipyretic (it lowers fever). It is restricted to adults, adolescents, and children weighing more than 33 kg. It is indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever.

2. Before you use MakoAche 10 mg/ml, solution for infusion

Do not use MakoAche 10 mg/ml, solution for infusion:

- If you are allergic (hypersensitive) to paracetamol or to any of the other ingredients of **MakoAche**,
- If you are allergic (hypersensitive) to propacetamol (another analgesic for infusion and a precursor of paracetamol),
- If you suffer from a severe liver disease.

Take special care with MakoAche 10 mg/ml, solution for infusion:

Use a suitable analgesic oral treatment as soon as this administration route is possible.

- If you suffer from a liver or kidney disease, or from alcohol abuse,
- If you are taking other medicines containing paracetamol,
- In cases of nutrition problems (malnutrition) or dehydration.

Inform your doctor before treatment if any of the above mentioned conditions apply to you.

Taking or using other medicines:

This medicine contains paracetamol and this must be taken into account if other medicines containing paracetamol or propacetamol are taken, in order not to exceed the recommended daily dose (see following section). Inform your doctor if you are taking other medicines containing paracetamol or propacetamol.

A dose reduction should be considered for concomitant treatment with probenecid. Please inform your doctor or pharmacist if you are taking oral anticoagulants. Closer check-ups of the effect of the anticoagulant might be needed.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Pregnancy and Breast-feeding

Pregnancy: Inform your doctor if you are pregnant. **MakoAche** may be used during pregnancy. However, in this case the doctor must evaluate if the treatment is advisable.

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

Breast-feeding: **MakoAche** may be used during breast-feeding.

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

Important information about some of the ingredients of MakoAche 10 mg/ml, solution for infusion

This medicinal product contains less than 1 mmol sodium (23mg) per 100 ml of **MakoAche** i.e. essentially "sodium free".

3. How to use MakoAche 10 mg/ml, solution for infusion

Intravenous use.

It is restricted to adults, adolescents, and children weighing more than 33 kg.

Close monitoring is needed before the end of infusion.

Dosage

Adolescents and adults weighing more than 50 kg:

1g of paracetamol per administration, i.e. a 100ml vial, up to 4 times a day.

Leave an interval of at least 4 hours between administrations.

The maximum dose must not exceed 4g of paracetamol per day, taking into account all the medicines containing paracetamol or propacetamol.

Children weighing more than 33 kg (about 11 years old), adolescents, and adults weighing less than 50 kg:

The dose is 15mg/kg paracetamol per administration, i.e. 1.5ml solution per kg, up to 4 times a day.

Leave an interval of at least 4 hours between administrations.

The maximum daily dose must not exceed 60mg of paracetamol per kilo and 3g of paracetamol per day, taking into account all the medicines containing paracetamol or propacetamol.

Do not Exceed the Stated Dose.

Method of administration

The paracetamol solution is administered in intravenous infusion over 15 minutes. A 0.8mm needle has to be used and the stopper vertically perforated at the spot specifically indicated.

In children, the volume of solution to be infused is 1.5ml per kg per administration. It can also be diluted in 0.9% sodium chloride or 5% glucose up to one tenth.

The diluted solution should be visually inspected and must not be used if opalescence, visible particulate matter, or precipitate are found.

If you have the impression that the effect of MakoAche 10 mg/ml, solution for infusion is too strong or too weak, talk to your doctor.

If you use more MakoAche 10 mg/ml, solution for infusion than you should, talk to your doctor or pharmacist immediately. In overdose cases, symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor, abdominal pain, and a risk of liver injury.

If you have any further questions on the use of this product ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, **MakoAche** 10 mg/ml, solution for infusion can cause side effects, although not everybody gets them:

- In rare cases (more than 1 out of 10,000 persons and less than 1 out of 1,000 persons), the following may occur: a malaise, a drop in blood pressure, or changes in laboratory test results: abnormally high levels of hepatic enzymes found during blood checks. Should this occur, inform your doctor as regular blood checks may be required later.

- In very rare cases (less than 1 out of 10,000 persons, including isolated reports) a serious skin rash or allergic reaction may occur. Stop the treatment immediately and inform your doctor.

- In isolated cases, other changes in laboratory test results have been observed which have necessitated regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells) can occur, possibly leading to bleeding from the nose or gums. Should this occur, inform your doctor.

- Cases of redness of the skin, flushing, itching, and abnormally rapid beating of the heart have been reported.

- Cases of pain and burning sensation at injection site have been reported.

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

5. How to store MakoAche 10 mg/ml, solution for infusion

Keep out of reach of children.

Do not use **MakoAche** 10 mg/ml, solution for infusion after the expiry date which is stated on the packaging. The expiry date refers to the last day of the month.

Store below 30°C.

Do not refrigerate or freeze.

Before administration, the product should be inspected visually. Do not use **MakoAche** if you notice any particulate matter and discolouration.

For single use only. The product should be used immediately after opening. Any unused solution should be discarded.

6. Further information

What MakoAche 10 mg/ml, solution for infusion contains:

The active substance is paracetamol. One ml contains 10mg paracetamol, this vial contains 1g paracetamol in 100ml.

The other ingredients are: Dimethylacetamide, mannitol, disodium edetate, sodium metabisulphite, hydrochloric acid, sodium hydroxide, water for injections, and nitrogen.

What MakoAche 10 mg/ml, solution for infusion looks like and contents of the pack

Vial of 100ml.

MakoAche 10 mg/ml, solution for infusion is a clear and slightly yellowish solution.

MakoAche 10 mg/ml, solution for infusion vials are supplied in packs of 1, 10 vials.

**Manufactured by: Solupharm pharmazeutische erzeugnisse GmbH,
Melfungen, Germany**

**For: ARWAN Pharmaceutical Industries Lebanon s.a.l.
Jadra, Lebanon**

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists