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 only. Do not pass it on to others. It may harm them, even their signs of illness 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.

What is in this leaflet
1. What MORPHINE HCl STEROP is and what it is used for
2. What you need to know before you use MORPHINE HCl STEROP
3. How to use MORPHINE HCl STEROP
4. Possible side effects
5. How to store MORPHINE HCl STEROP
6. Contents of the pack and other information

1. WHAT MORPHINE HCl STEROP IS AND WHAT IT IS USED FOR

MORPHINE HCl STEROP is a morphine analgesic indicated for the treatment of intense pain that cannot be relieved by lower-level analgesics.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MORPHINE HCl STEROP

Do not use MORPHINE HCl STEROP:
- If you are allergic to morphine.
- If you suffer from impaired lung function.
- If you suffer from an acute abdominal syndrome of unknown aetiology.
- If you suffer from digestive tract spasms and severe liver failure.
- If you suffer from a cranial trauma, excessively high intracranial pressure, convulsions or a coma.
- If you suffer from alcohol poisoning or acute alcoholism, or barbiturate poisoning.
- Do not administer as preoperative medication in children under the age of 1 year or in premature infants.

Warnings and precautions
Morphine is a narcotic that can cause drug addiction; physical and psychological dependence and habituation can develop following repeated administrations.
The abrupt discontinuation of prolonged treatment causes withdrawal symptoms: discontinuation should therefore be gradual and depends on the duration of treatment, the dose administered and the patient's pain levels. A withdrawal syndrome occurring following the discontinuation of prolonged treatment is characterised by the following signs: abnormal increase in pupil diameter, tearing, nasal discharge, sneezing, muscle tremor, weakness, sweating, anxiety, irritability, insomnia, nausea, vomiting, diarrhoea, dehydration, reduced plasma volume and leukocytosis, abdominal and muscle cramps, heart disorders, elevated body temperature, high blood pressure.

- Caution is necessary during the treatment of patients with a history of dependence on psychotropic drugs.
- Morphine should not be administered preoperatively to children below the age of 1 year and should be given with extreme caution to neonates and premature infants. The initial dose must be reduced and the patient monitored in an Intensive Care Unit for the treatment of acute pain, with the preparation of an antidote.
- The dosage should be reduced in elderly or frail patients, particularly in the event of kidney and liver insufficiency given their particular sensitivity to analgesic effects and central or digestive undesirable effects.
- Morphine should be administered with care in patients suffering from poor functioning of the thyroid gland, adrenal glands, liver, kidneys, prostate, in patients in a state of shock or in the event of elevated intracranial pressure.
- The respiratory function of patients with respiratory insufficiency should be monitored. Drowsiness constitutes a warning sign of decompensation.
- It is essential to determine and manage any constipation or occlusive syndrome before and during the treatment.
- In the event of hypovolemia, morphine may trigger a collapse. Hypovolemia should be corrected before injecting morphine.
- In the event of recent or current treatment with an MAO inhibitor.
- MORPHINE HCl STEROP does not contain any preservatives and micro-organisms may therefore proliferate after the ampoules are opened. The drug preparation solution, and any syringe containing it, are for single and individual use, and should never be reused.
- If you need to inject MORPHINE HCl STEROP, a sterile syringe should be used and the solution should be drawn immediately after the ampoule is opened. The entry of any micro-organisms should be prevented. Any quantity of unused or remaining drug solution must be discarded in compliance with current regulations.
- If you need to use the drug solution in an infusion, this solution and the infusion equipment should be protected from any microbial contamination throughout the duration of the infusion. At the end of the infusion, any remaining drug solution, and all equipment containing it, must be eliminated in compliance with current regulations. Outside a hospital, it is recommended not to use an infusion for more than 4 to 6 hours.
- There is a risk of irritation or necrosis at the site of the injection, or thrombophlebitis if the administration is too rapid or prolonged. In order to reduce the risk of thrombophlebitis, it is recommended to change the site of administration every 24 hours.
- Do not use the solution if it is not clear.

If you are already taking other medicines, please also read section “Other medicines and MORPHINE HCl STEROP”.
Please consult your doctor if any of the warnings mentioned above applies to you, or if any of them have in the past.
Other medicines and MORPHINE HCl STEROP
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Do not administer morphine at the same time as:
- Other morphine derivatives, benzodiazepines, barbiturates: increased risk of respiratory depression.
- The depressant effects of morphine are enhanced by central nervous system depressants: anaesthetics, anxiolytics and hypnotics, sedative antidepressants and H1 antihistamines, phenothiazines, neuroleptics, central antihypertensive agents, thalidomide, baclofen.
- Morphine agonists-antagonists (buprenorphine, nalbufine, pentazocine): reduction of the analgesic or antitussive effect through the competitive blockade of receptors, with a risk of onset of withdrawal syndrome.
- Rifampicin: reduction in the concentrations and efficacy of morphine and its active metabolite. Clinical surveillance and adaptation if necessary of the morphine dosage during treatment with rifampicin and after its discontinuation are essential.
- If MAO inhibitors (a type of antidepressant) are administered at the same time, this may enhance the sedative effect and lower blood pressure.

Morphine hydrochloride solutions are incompatible with bases, iodine and iron, lead, manganese, silver, copper and zinc salts, tannic acid and potassium permanganate.

MORPHINE HCl STEROP with food, drink and alcohol
Avoid the consumption of alcoholic drinks and medicines containing alcohol: the sedative effects of morphine compounds are enhanced by alcohol and may impair alertness.

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.

A moderate quantity of data concerning pregnant women has not indicated that morphine causes malformations of the foetus/newborn. For reasons of safety, it is preferable not to use morphine during pregnancy.
Morphine crosses the placental barrier and may cause respiratory depression in a newborn infant.
Dependence and a withdrawal syndrome may appear in the newborn if the mother is a drug addict, with irritability, vomiting, convulsions and an increased risk of fatality. In this case, neonatal monitoring should be envisaged.

Information concerning the excretion of morphine in breast milk is insufficient. The risks for a breastfed infant cannot be excluded. Discontinuation of the treatment, or of breastfeeding, should be considered, taking account of the benefits of breastfeeding to the infant and the advantages of therapy for the mother.

Driving and using machines
Because of impaired alertness and the depressant effect of morphine on the central nervous system, patients receiving this medicinal product should abstain from driving vehicles and using tools and/or machines for 48 hours after the last injection.
3. **HOW TO USE MORPHINE HCl STEROP**

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

As an injection under the skin, in a muscle or into a vein, and also as an intrathecal (epidural or intraspinal) and intraventricular injection. The physician will determine the quantity to be injected, the frequency of injections and the route of administration, depending on the patient and on the effects sought. The physician will also explain the instructions for use.

Do not stop your treatment early because your state of health may suffer.

**If you use more MORPHINE HCl STEROP than you should**

If you used too much MORPHINE HCl STEROP, contact your doctor, your pharmacist or the Poison Center (070/245.245).

The symptoms of overdose include: drowsiness, which may be followed by breathing difficulties, marked shrinkage of the pupils, a drop in blood pressure, a drop in body temperature, coma.

Emergency treatment should preferably be given in a specialised hospital and will include: the discontinuation of current morphine therapy, cardiac and respiratory resuscitation, specific therapy with morphine antagonists: administer naloxone 0,4mg via the intravenous route, to be repeated every 2 to 5 minutes if necessary (0,4 to 4mg in fractionated doses). In children, the initial dose is 0,01mg/kg. If no effect is observed after 2 to 3 doses, the diagnosis can reasonably be called into question.

Precaution: in individuals dependent on morphinomimetics, the injection of too large a quantity of naloxone may trigger a withdrawal syndrome (see Undesirable Effects). In these patients, naloxone should be injected cautiously at gradually increasing doses.

**If you forget to use MORPHINE HCl STEROP**

Do not take a double dose to make up for a forgotten dose.

**If you stop using MORPHINE HCl STEROP**

Because morphine is an analgesic that can cause a state of dependence during prolonged use, the patient must not discontinue treatment abruptly, as a withdrawal effect may appear. The patient's physician should be consulted first of all to obtain an explanation on how to gradually taper the dosage.

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

4. **POSSIBLE SIDE EFFECTS**

Like all medicines, MORPHINE HCl STEROP can cause side effects, although not everybody gets them.

The frequency of possible side effects is defined as follows:
The following side effects may be observed during treatment:

**Very common:**
- Risk of physical and psychological dependence as a function of the dose and duration, causing withdrawal syndrome following any abrupt discontinuation of the medicinal product. The signs of withdrawal include: dilation of the pupils, continuous tearing and nasal discharge, sneezing, muscle tremor, weakness, sweating, anxiety, irritability, insomnia, nausea, vomiting, diarrhoea, dehydration, concentration of the blood and rise in the white blood cell count, abdominal and muscle cramps, accelerated heart rate, elevation of body temperature, rise in blood pressure.
- Constipation, nausea.

**Uncommon:**
- Sedation, confusion, nightmare, hallucinations, excitation, drowsiness.
- Itching, urticaria, skin rashes.
- Pain or irritation at the injection site.

**Rare:**
- Excessive intracranial pressure.
- Difficulty breathing, apnoea.
- Vomiting.
- Difficulty urinating.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. **HOW TO STORE MORPHINE HCl STEROP**
Keep out of the sight and reach of children.  
Protect from light.

Do not use MORPHINE HCl STEROP after the expiry date which is stated on the pack and the ampoule after the mention "EXP". The expiry date refers to the last day of that month.

Do not use MORPHINE HCl STEROP if you notice the presence of particles in the ampoule.

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 MORPHINE HCl STEROP contains
- The active substance is morphine hydrochloride 10mg, 20mg, 30mg or 40mg by ml.
- The other ingredients are: sodium chloride, hydrochloric acid and water for injection.

What MORPHINE HCl STEROP looks like and contents of the pack
Solution for injection

Subcutaneous, intramuscular, intravenous and intrathecal use.

1ml uncoloured glass ampoules type I, packaged in boxes of 10 and 100 ampoules.

Prescription : On medical prescription.
MORPHINE HCl STEROP follows the law for narcotics.

Numbers of Authorisation on the market :
MORPHINE HCl STEROP 10mg/1ml : BE414346
MORPHINE HCl STEROP 20mg/1ml : BE414355
MORPHINE HCl STEROP 30mg/1ml : BE414364
MORPHINE HCl STEROP 40mg/1ml : BE414373

Marketing Authorisation Holder and Manufacturer
LABORATOIRES STEROP - Avenue de Scheut 46-50 - 1070 Brussels.

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