

Information for the Patient

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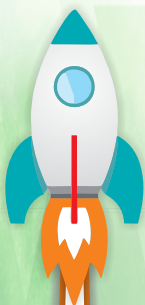


Hyperbaric solution of Ropivacaine

ROPIN[®] Heavy

Preservative not added Ropivacaine Hydrochloride in Dextrose Inj

Safe and reliable for spinal Anaesthesia



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Read this entire leaflet carefully. It is about a drug called Ropivacaine Hydrochloride in Dextrose Inj. which may be given to you during the anaesthesia for your surgery. **Ropin Heavy is its brand name.**

This leaflet contains important information about a drug called Ropivacaine Hydrochloride in Dextrose Injection.

Please keep this leaflet carefully with you because you may need it to read again and again.

Do not hesitate to ask your doctor for any doubts/ queries about this drug, or if you specifically want to know about following:

1. Side effects of this drug, as described in the leaflet provided to you OR
2. Any other side effects that you heard about OR
3. Any side effects which you may think about.

Please talk to your doctor, nurse or pharmacist and get clarification about Ropivacaine Hydrochloride in Dextrose Inj. from them on following queries:

1. What is Ropivacaine Hydrochloride in Dextrose Inj. and what is it used for?

Ropin Heavy contains a drug called Ropivacaine Hydrochloride in Dextrose Inj. This belongs to a group of drugs called local anaesthetics.

Ropivacaine Hydrochloride in Dextrose Inj. is used:

To block or stop all sensations viz. pain, pressure, touch, temperature of the lower abdominal organs and/or lower limbs i.e. to make these parts of lower body numb (to anaesthetise) during surgery in adults and children.

With this numbness or anaesthesia the surgery on these parts is done without any pain or discomfort to the patient. After the action of the drug is over, the patient regains all the sensations of the parts which were numb or anaesthetised.

2. How Ropin Heavy (Ropivacaine Hydrochloride in Dextrose Inj.) is given?

You will never be expected to take this medicine by yourself. It will always be given to you by a specialist called anaesthesiologist. If the surgery is planned under spinal anaesthesia, the required dose of Ropivacaine Hydrochloride in Dextrose Inj. for you, will be calculated depending on your age and weight by the anaesthesiologist. The calculated dose of Ropivacaine Hydrochloride in Dextrose Inj. is slowly injected into lower back through the space between two spines under strict aseptic precautions.

After injecting Ropivacaine Hydrochloride in Dextrose Inj. you will not be able to feel any pain during the surgery.

3. What you must inform to your doctor before you are given Ropin Heavy (Ropivacaine Hydrochloride in Dextrose Inj.)?

If you are likely to undergo some surgery under spinal anaesthesia, talk to your doctor and inform him whether in the past you had any one of the following conditions:

1. Whether you are allergic to Ropivacaine hydrochloride in dextrose or any of the other ingredients of this medicine.
2. Whether you are allergic to any other local anaesthetics of the same class (such as Lidocaine or Ropivacaine).

3. Whether you are allergic to any other medicine or any substance.
4. Whether you have skin infection on your back, especially on the lower back.
5. Whether recently you have suffered any acute heart illness such as acute heart attack or cardiogenic shock (a serious condition where the heart is unable to supply enough blood to the body).
6. Whether recently you had severe blood loss or fluid loss due to any cause resulting into something called hypovolemic shock (very low blood pressure leading to collapse).

4. What other information you must give to your doctor if you are likely to be given Ropin Heavy (Ropivacaine Hydrochloride in Dextrose Inj.)?

a) Please inform your doctor if you are taking or have recently taken any of the following medicines:

1. Anaesthesia of any type in the past.
2. Antibiotics (used to treat infections).
3. Drugs for irregular heart beat (anti-arrhythmic).
4. Drugs for high blood pressure.
5. Diuretic drugs such as furosemide.
6. Drugs for inflammation of the joints such as chloroquine or d-penicillamine.
7. Steroids.
8. Drugs for fits (epilepsy), such as phenytoin or carbamazepine.
9. Drugs for mental illness, such as lithium or chlorpromazine.
10. Drugs containing magnesium.
11. Drugs for Alzheimer's disease (anticholinesterases e.g. Donepezil).
12. Any herbal products or medicines bought without a prescription.

b) Pregnancy and breast-feeding:

If you are pregnant or breast-feeding OR if you think that you may be pregnant or are planning to have a baby, please inform your doctor.

5. What are the possible side effects and adverse reactions?

Possible side effects:

Like all other medicines, Ropivacaine Hydrochloride in Dextrose Injection can cause side effects, although not everybody gets them. Allergic reactions are observed in less than 1 in 1000 individuals which include:

1. Swelling of the face, lips, tongue or throat. This may make it difficult to swallow.
2. Severe or sudden swelling of hands, feet and ankles.
3. Difficulty in breathing.
4. Severe itching of the skin (with raised lumps).
5. Very low blood pressure which can make you feel faint or collapse.

Adverse Reactions:

In the literature, low blood pressure, feeling sick (nausea), slow heartbeat, headache, being sick (vomiting), difficulty in passing urine or being incontinent, itching, numbness, burning or tingling of the skin, back pain, muscle weakness for a short time, heart attack, difficulty in breathing, weakness or loss of feeling or loss of movement in your lower body, long-lasting pain in your back or legs, reduced or strange sensation or feeling in the skin have been reported.

6. How to store Ropivacaine Hydrochloride in Dextrose Inj. (Ropin Heavy)?

- ▶ 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 as EXP. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C.

Your doctor or the hospital will normally store Ropivacaine Hydrochloride in Dextrose Inj. and they are responsible for the quality of the product when it has been opened and if it is not used immediately. They are also responsible for disposing of any unused Ropivacaine Hydrochloride in Dextrose Inj. correctly.

Ask your doctor if you need further explanation about this drug.



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