SCHEDULING STATUS S4

PROPRIETARY NAME, STREGNTH AND PHARMACEUTICAL FORM

ADCO ROPIVACAINE 200 mg/100 ml (Infusion solution)

Read all of this leaflet carefully before you are given ADCO ROPIVACAINE 200 mg/100 ml

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ADCO ROPIVACAINE 200 mg/100 ml** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT ADCO ROPIVACAINE 200 mg/100 ml CONTAINS

Each 100 ml of solution contains ropivacaine hydrochloride monohydrate equivalent to ropivacaine hydrochloride 200, 00 mg.

Sugar free

The inactive ingredients are: sodium chloride, sodium hydroxide, hydrochloric acid and water for injections.

WHAT ADCO ROPIVACAINE 200 mg/100 ml IS USED FOR

ADCO ROPIVACAINE 200 mg/100 ml is an anaesthetic (numbing medicine), that blocks the nerve impulses that send pain signals to your brain, and thus produces total loss of physical sensation.

ADCO ROPIVACAINE 200 mg/100 ml is used to provide anaesthesia during surgery and is used in pain management.

ADCO ROPIVACAINE 200 mg/100 ml is to be given only by your doctor.

BEFORE YOU ARE ADMINISTERED ADCO ROPIVACAINE 200 mg/100 ml

You should not be administered ADCO ROPIVACAINE 200 mg/100 ml:

- if you have ever had an allergic reaction to any type of local anaesthetic (numbing medicine)
- If you are allergic to **ADCO ROPIVACAINE 200 mg/100 ml**, ropivacaine hydrochloride, or to any other ingredients used in **ADCO ROPIVACAINE 200 mg/100 ml** (see **WHAT ADCO ROPIVACAINE 200 mg/100 ml CONTAINS**)
- **ADCO ROPIVACAINE 200 mg/100 ml** should not be given to:
    - Children under the age of 1 year.
    - Pregnant or breastfeeding women
    - Patients with untreated low blood pressure
    - Patients with inflammation and sepsis at the injection site

Tell your doctor or healthcare professional before being given the injection if:

TAKE SPECIAL CARE WITH ADCO ROPIVACAINE 200 mg/100 ml:

- If you taking heparin (blood thinning medicine).
- If you are taking amiodarone, a medicine used to treat abnormal heartbeats.
- If you are taking verapamil (medicine for treating blood pressure)
- If you are taking fluvoxamine (medicine for treating depression)
- If you have existing neurological disease e.g. myasthenia gravis (muscular disease)
- If you have existing central nervous system or spinal cord diseases e.g. meningitis, tumours, etc.
- if you have:

  liver disease;

  heart disease; or

  kidney disease.

  If you have any of these conditions, you may need a dose adjustment.

Pregnancy and Breast-feeding:

Safety in pregnancy and lactation has not been established.

ADCO ROPIVACAINE 200 mg/100 ml is not recommended in pregnancy or woman breast-feeding, except when used in labour.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care provider for advice before being given ADCO ROPIVACAINE 200 mg/100 ml

Driving and using machinery:

- **ADCO ROPIVACAINE 200 mg/100 ml** may affect your mental functioning, co-ordination and may impair locomotion and alertness.
- Do not drive and do not operate any tools or machine as **ADCO ROPIVACAINE 200 mg/100 ml** could interfere with your ability to drive safely

Taking other medicines with ADCO ROPIVACAINE 200 mg/100 ml:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines)

If you are taking any of the following medicines tell your doctor, pharmacist or other health care professional:

- ❖ NSAID's {(Non-steroidal anti-inflammatory drugs) used for pain and inflammation} (e.g. aspirin etc.), and other blood thinning medicines.
- ❖ Heparin (used for thinning the blood). When used together with **ADCO ROPIVACAINE 200 mg/100 ml** may cause temporary or permanent paralysis.
- ❖ Anti-dysrhythmic medicines (medicines use to treat certain heart conditions). Close surveillance and ECG monitoring is required.

HOW ADCO ROPIVACAINE 200 mg/100 ml IS ADMINISTERED:

This medicine should only be administered by your doctor. The dose will be different for different patients depending on your age.

ADCO ROPIVACAINE 200 mg/100 ml is a medicine for use in hospitals.

If you are given ADCO ROPIVACAINE 200 mg/100 ml than you should:

Your doctor or nurse will ensure that you will receive the correct dose. As signs of toxicity may be delayed, you will be monitored for a few hours. Signs of an accidental overdose might result in central nervous system symptoms such as visual and hearing disturbances, dizziness, muscular twitching and fits. Cardiovascular symptoms may also occur such as low blood pressure, an abnormal heart rhythm and even heart failure. Consult your doctor, if you think, you have been administered more **ADCO ROPIVACAINE 200 mg/100 ml** than you should.

POSSIBLE SIDE EFFECTS

Not all side-effects reported for ADCO ROPIVACAINE 200 mg/100 ml are included in this leaflet. Should your general health worsen or you experience any untoward effects while receiving ADCO ROPIVACAINE 200 mg/100 ml, please consult your healthcare provider for advice.

The following side effects have been reported and may occur with **ADCO ROPIVACAINE 200 mg/100 ml.**

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Abnormal or irregular heart beat;
- Allergic reactions (swelling and itching); numbness of the tongue; swelling of throat and lips; difficulty with swallowing and breathing
- Headache;
- Dizziness;
- Seizures or fits;
- Visual and hearing disorders;
- Muscular twitching;
- Speech disorders
- Anxiety or restlessness

- Abnormal blood pressure, either too low or too high. Loss of consciousness due to low blood pressure.

These are all serious side-effects of **ADCO ROPIVACAINE 200 mg/100 ml**. You may need urgent medical attention or discontinuation of treatment.

Tell your doctor if you notice any of the following:

- Nausea and vomiting
- High or low temperature;
- Back pain
- Urinary retention (involuntary accumulation of urine in the bladder)
- Difficulty breathing
- Pruritus (itching)
- Tingling sensation
- Light headedness

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ADCO ROPIVACAINE 200 mg/100 ml

Store at or below 25 ^{0}C.

Do not freeze.

Discard remaining contents after use.

Store all medicines out of reach of children.

Your pharmacist, doctor or other health care professional will dispose of it.

PRESENTATION OF ADCO ROPIVACAINE 200 mg/100 ml

100 ml or 200 ml plastic infusion bag (PVC), enclosed in a high density polyethylene overpouch.

Five (5) individual units are packed in an outer carton.

IDENTIFICATION OF ADCO ROPIVACAINE 200 mg/100 ml

A sterile isotonic clear and colourless solution.

REGISTRATION NUMBER

43/4/0525

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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