

MARCAIN with FENTANYL

Bupivacaine hydrochloride with fentanyl citrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about MARCAIN with FENTANYL. It does not contain all the information that is known about MARCAIN with FENTANYL.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you being given MARCAIN with FENTANYL against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What MARCAIN with FENTANYL is for

MARCAIN with FENTANYL is used after surgery to treat post-operative pain.

It can also be used to make childbirth less painful.

MARCAIN belongs to a group of medicines called local anaesthetics. When injected, it makes the nerves nearby unable to pass messages to the brain and will therefore prevent or relieve pain.

FENTANYL belongs to a group of medicines called narcotic analgesics. It is a powerful drug used to relieve pain.

MARCAIN with FENTANYL is a combination of the two drugs and

produces anaesthesia (loss of feeling) and analgesia (pain relief).

Your doctor will have explained why you are being treated with MARCAIN with FENTANYL and told you what dose you will be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

As it contains fentanyl, MARCAIN with FENTANYL can be addictive, but when it is used only to relieve or prevent pain it is unlikely to become habit forming.

Before you are given MARCAIN with FENTANYL

When you must not have it

Ask your doctor about the risks and benefits of being given MARCAIN with FENTANYL while you are pregnant or breastfeeding.

We do not know if it is safe for you to be given it while you are pregnant. However, it can be used during childbirth.

Your baby can take in very small amounts of MARCAIN with FENTANYL from breast milk if you are breastfeeding, but it is unlikely that the amount available to the baby will do any harm.

MARCAIN with FENTANYL will only be used if the solution is

clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

MARCAIN with FENTANYL is not recommended for use in children.

There is only limited information about its use in children.

Before you are given it

You must tell your doctor if:

1. you have any allergies to

- any ingredients listed at the end of this leaflet
- other local anaesthetics e.g. lignocaine
- other strong pain killers e.g. morphine or pethidine

If you have an allergic reaction, you may get a skin rash, hay fever or an asthma attack.

2. you have any of these medical conditions

- problems with your blood pressure or circulation
- problems with the clotting of your blood, blood poisoning
- heart, nerve, liver or kidney problems
- diseases of the cerebrospinal system, such as meningitis, tumours, poliomyelitis, degeneration of the spinal cord
- certain conditions of the back e.g. tumours, osteomyelitis, arthritis and spondylitis
- problems with your breathing such as severe asthma, severe bronchitis or emphysema
- a history of fits or head injuries
- neuromuscular disease e.g. myasthenia gravis (muscle weakness)

- thyroid problems

It may not be safe for you to be given MARCAIN with FENTANYL if you have any of these conditions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

- medicines used to treat irregular heart beats, e.g. mexiletine, lignocaine or amiodarone
- low molecular weight heparin or other medicines used to prevent blood clots.
- sedatives, sleeping tablets
- antidepressant treatment with monoamine oxidase (MAO) inhibitors, e.g. tranylcypromine, even if you are within 14 days of stopping such treatment; Other anti-depressant drugs, migraine medicines and sibutramine (medicines for weight loss). Taking these medicines with MARCAIN with FENTANYL may cause a serious condition called Serotonin Syndrome (a sudden increase in body temperature, very high blood pressure, rigid muscles, mental status changes, nausea, vomiting and/ or fits)
- medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way MARCAIN with FENTANYL works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you are given any MARCAIN with FENTANYL.

How MARCAIN with FENTANYL is given

MARCAIN with FENTANYL will be injected by your doctor into the

epidural space, near your spinal cord, through a space between vertebrae in your lower back. A thin tube will be inserted so a continuous dose can be given over a period of time.

This is called an EPIDURAL INFUSION and it will result in a feeling of numbness in your lower body, in an area that may seem unrelated to the site of injection.

MARCAIN with FENTANYL should not be injected directly into the blood.

The dosage you will be given will depend on your body size, age and the type of pain relief required.

Your doctor will have had a lot of experience injecting MARCAIN with FENTANYL or other similar drugs and will choose the best dose for you. They will be willing to discuss this decision with you.

Overdose (taking too much)

The doctor giving you MARCAIN with FENTANYL will be experienced in the use of this type of drug, so it is unlikely that you will be given an overdose.

However, if you are particularly sensitive to MARCAIN with FENTANYL, or the dose is accidentally injected directly into your blood, you may develop problems for a short time with your sight or hearing. You may get a numb feeling in or around the mouth, feel dizzy or stiff, or have twitchy muscles.

Whenever you are given MARCAIN with FENTANYL, equipment will be available to care for you if an overdose happens.

While you are being given it

Things to be careful of

Be careful driving or operating machinery after you have been

given MARCAIN with FENTANYL.

You may be drowsy and your reflexes may be slow.

Do not drink alcohol while you are being given MARCAIN with FENTANYL.

If you drink alcohol while you are being given MARCAIN with FENTANYL your blood pressure may drop making you feel dizzy and faint.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given MARCAIN with FENTANYL.

MARCAIN with FENTANYL will prevent or relieve pain in most people, but it may have unwanted side-effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- nervousness
- dizziness
- blurred vision
- drowsiness
- ringing in the ears
- numbness
- feeling strange (disoriented)
- nausea (feeling sick), vomiting
- constipation
- itching

These are all mild side effects of MARCAIN with FENTANYL.

After an epidural injection you may develop a headache or backache

which is not related to the medicine used. These can, on rare occasions, last for some months after the injection is given.

If MARCAIN with FENTANYL is given wrongly, or you are very sensitive to it, it sometimes causes

- fits
- unconsciousness
- breathing problems
- low blood pressure
- slow heart beat
- clammy and cold skin
- collapse

These are all serious side effects. You may need urgent medical attention

Some people may get other side effects while being given MARCAIN with FENTANYL.

Tell your doctor if you notice anything else that is making you feel unwell.

After using it

Storage

MARCAIN with FENTANYL will be stored by your doctor or pharmacist under the recommended conditions.

It should be kept in a cool dry place where the temperature stays below 30 degrees C.

Disposal

Any MARCAIN with FENTANYL which is not used will be disposed of in a safe manner by your doctor or pharmacist.

Product description

Each MARCAIN with FENTANYL contains Bupivacaine hydrochloride 1.25 mg/mL (as monohydrate) plus

fentanyl 5 microgram/mL (as citrate) as the active ingredients, plus

Sodium Chloride

Sodium Hydroxide or Hydrochloric Acid for pH adjustment

Water for Injections

MARCAIN with FENTANYL is available as 20mL polypropylene ampoules in sterile theatre packs.

Sponsor

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

MARCAIN (1.25 mg/mL) with FENTANYL (5 microgram/mL)

20 mL ampoule Aust R 123384

This leaflet was revised in Sep 2018

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