1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S6

PROPRIETARY NAME AND DOSAGE FORM

FORTIVA 1 mg

Injection

FORTIVA 2 mg

Injection

FORTIVA 5 mg

Injection

Read all of this leaflet carefully before you are given FORTIVA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- FORTIVA 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 FORTIVA CONTAINS

The active substance in each vial of FORTIVA 1 mg, is 1 mg remifentanil base as remifentanil hydrochloride.

The active substance in each vial of FORTIVA 2 mg, is 2 mg remifentanil base as remifentanil

hydrochloride.

The active substance in each vial of FORTIVA 5 mg, is 5 mg remifentanil base as remifentanil hydrochloride.

The other ingredient is glycine.

Sugar free

WHAT FORTIVA IS USED FOR

Remifentanil, as contained in FORTIVA, belongs to a group of medicines called opioids. These medicines are widely used to produce anaesthesia and/or relieve pain during an operation.

Your doctor has chosen this medicine to suit the type of operation you are having.

FORTIVA injection should be used, together with other medicines, to produce and/or maintain anaesthesia and relieve any pain immediately following your operation.

BEFORE YOU ARE GIVEN FORTIVA

If you answer “Yes” to any of the following questions, tell your doctor about this before your operation.

- Have you had any adverse reaction during an operation?
- Have you been told that you are allergic to any medicines used during an operation?
- Have you ever had any problems with your breathing?
- Do you have a slow or irregular heart beat?

- Have you ever been told your blood pressure is low?
- Have you recently been taking other types of medicines known as beta-blockers or calcium channel blockers?
- Are you pregnant, or likely to become pregnant soon?
- Are you breastfeeding?

Make sure that your doctor knows what other medicines you are taking.

Pregnancy and breastfeeding

Always tell your healthcare provider if you are using any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before receiving FORTIVA.

Taking/Giving/Using other medicines with FORTIVA

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

HOW TO RECEIVE FORTIVA

Do not share medicines prescribed for you with any other person.

You will never be expected to give yourself FORTIVA. It will always be given to you by a person who is qualified to do so. The dosage will depend on the operation you have.

If you receive more FORTIVA than you should

Since a healthcare provider will administer this medicine, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

POSSIBLE SIDE EFFECTS

FORTIVA may cause side effects.

Some people can be allergic to medicines. You may experience the following symptoms:

- sudden wheeziness and chest pain or chest tightness;
- swelling of eyelids, face, lips, mouth or tongue;
- lumpy skin rash or “hives” anywhere on the body.

Tell your doctor as soon as possible if you experience any of the following:

- slowing of heartbeat, dizziness, tiredness or fainting;
- increased blood pressure which may cause a headache or sensation of warmth/flushing;
- breathlessness;
- muscle stiffness;
- aches;
- shivering;
- nausea;
- vomiting;
- constipation;
- drowsiness.

If you have any other symptoms that you do not understand, tell your doctor.

Not all side effects reported for FORTIVA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving FORTIVA, please consult your healthcare provider for advice.

STORING AND DISPOSING OF FORTIVA

You will not be required to store this medicine prior to use.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

The reconstituted solution is stable for 24 hours at 25 °C.

Any unused portion must be discarded.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF FORTIVA

FORTIVA 1 mg: 3 ml clear, Type 1 glass vials with grey bromobutyl rubber stoppers and secured with an aluminium overseal with a light blue plastic flip-off top. The vials are placed in a carboard carton together with a leaflet.

FORTIVA 2 mg: 5 ml clear, Type 1 glass vials with grey bromobutyl rubber stoppers and secured with an aluminium overseal with a royal blue plastic flip-off top. The vials are placed in a carboard carton together with a leaflet.

FORTIVA 5 mg: 10 ml clear, Type 1 glass vials with grey bromobutyl rubber stoppers and secured with an aluminium overseal with a dark blue plastic flip-off top. The vials are placed in a carboard carton together with a leaflet.

Not all strengths, packs and pack sizes are necessarily marketed.

IDENTIFICATION OF FORTIVA

White to off-white cake that may be intact or fragmented.

Reconstituted solutions are a clear and colourless liquid, practically free from particulate matter.

REGISTRATION NUMBER

FORTIVA 1 mg: 42/2.9/0751

FORTIVA 2 mg: 42/2.9/0752

FORTIVA 5 mg: 42/2.9/0753

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

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Hotline: 0800 122 912

DATE OF PUBLICATION

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Date of the most recent amendment to the patient information leaflet as approved by the Authority: 26 November 2010

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