PACKAGE LEAFLET: INFORMATION FOR THE USER

Dehydrated Alcohol (Absolute Alcohol) **BP for Injection**

Ethanol BP

Read all of this leaflet carefully before you are given this

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor
- · 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 nurse.

In this leaflet:

- 1. What Dehydrated Alcohol for Injection is and what it is used for
- 2. Before you are given Dehydrated Alcohol for Injection
- 3. How Dehydrated Alcohol for Injection will be given
- Possible side effects
- 5. How to store Dehydrated Alcohol for Injection
- 6. Further information

1. What Dehydrated Alcohol for Injection is and what it is used for

• Dehydrated Alcohol (Absolute alcohol) BP for Injection is a sterile solution of 100 % ethanol.

- severe pain including trigeminal neuralgia (a severe pain in the jaw, lips, eyes and face)
- · methanol poisoning.

2. Before you are given Dehydrated Alcohol for Injection

You should NOT be given Dehydrated Alcohol for Injection if:

· you are allergic (hypersensitive) to ethanol.

Take special care with Dehydrated Alcohol Tell your doctor if:

· you are pregnant or breast feeding

Taking other medicines:

Tell your doctor if you are taking any of the following:

- sleep-inducing drugs such as nitrazepam
- · antihistamines such as chlorpheniramine or promethazine, used to treat allergies
- · muscle relaxants such as atracurium
- strong painkillers such as morphine
- · medicines used in the treatment of epilepsy, such as phenytoin
- · medicines used to treat depression such as amitriptyline or imipramine
- · tranquillisers used to treat anxiety such as diazepam
- insulin or oral antidiabetic tablets such as chlorpropamide, used to treat diabetes, as alcohol can also reduce blood glucose levels
- · metronidazole used to treat urinary tract infections
- cephalosporin antibiotics, such as cefalexin or cefaclor, used to treat infections
- anti hypertensive agents used to lower blood pressure (ACE inhibitors, beta-blockers and calcium channel blockers) such as ramipril, captopril, propranolol, atenolol, diltiazem and nifedipine.
- medicines used to thin the blood (anticoagulants), such as warfarin and acenocoumarol.

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding you should talk to your doctor before receiving this medicine.

Effects on the ability to drive and use machinery:

Alcohol affects your judgement and co-ordination. You should not drive or operate machinery if you have recently been given this medicine.

3. How Dehydrated Alcohol for Injection will be given

The doctor or nurse will give you this medicine. They will decide on how much will be given to you.

Treatment of severe pain (including trigeminal neuralgia): The dose will depend on the location and severity of the pain. The Dehydrated Alcohol will be given as an injection close to

the nerve. Methanol poisoning;

The Dehydrated Alcohol is given as an infusion (drip) into a vein over 30 minutes.

If you are given too much Dehydrated Alcohol for Injection: Dehydrated Alcohol for Injection will be given to you by a doctor, therefore it is unlikely that you will be given too much or that you will miss a dose. However, if you are concerned about your treatment, please talk to your doctor or nurse.

4. Possible side effects

Like all medicines Dehydrated Alcohol for Injection can cause side effects, although not everybody gets them.

If you experience any of the following please tell your doctor or nurse immediately. These are symptoms of an allergic reaction.

- · difficulty breathing or swallowing
- swelling of face, lips, throat or tongue
- skin rash

Side effects which may occur with low to moderate levels of alcohol are:

- loss of co-ordinated body movements (unsteadiness, clumsiness)
- · loss of judgement
- mood changes/swings
- blurred vision
- slurred speech.

Other side effects include:

- · drowsiness, loss of energy
- · memory loss
- · loss of body heat (feeling cold)
- low blood sugar levels (especially in children)
- · loss of consciousness or loss of awareness
- breathing difficulties
- coma
- · heart failure.

If any of the side effects gets serious, or you notice any side effects not listed in the leaflet, please tell your doctor or nurse.

5. How to store Dehydrated Alcohol for Injection Keep out of the reach and sight of children.

Do not use Dehydrated Alcohol for Injection after the expiry date which is stated on the ampoule and carton labels. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

6. Further Information

What Dehydrated Alcohol for Injection contains:

The active ingredient is ethanol 100% v/v. There are no other ingredients.

What Dehydrated Alcohol for Injection looks like and contents of the pack:

Dehydrated Alcohol for Injection is a clear colourless solution. The product is supplied in clear glass ampoules containing 2 ml, 5 ml, 10 ml, 20 ml or 50 ml of solution. Each pack contains 10 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Martindale Pharmaceuticals, Bampton Road, Harold Hill, Romford, RM3 8UG, UK

Product Licence Number: PL 01883/6119

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