PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PARADOTE (Concentrate solution for dilution for IV infusion)

Each 1 ml solution contains 200 mg acetylcysteine.

Read all of this leaflet carefully before you are given PARADOTE.

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

1. WHAT PARADOTE CONTAINS

Active ingredient: acetylcysteine.

Inactive ingredients: disodium edetate; sodium hydroxide and water for injection.

2. WHAT PARADOTE IS USED FOR

PARADOTE solution contains the active ingredient acetylcysteine which is an antidote that protects the liver from damage following paracetamol overdosage.

3. BEFORE YOU ARE GIVEN PARADOTE

Do not use PARADOTE:

− If you have a hypersensitivity to acetylcysteine or any of the excipients in the product.

Take special care with PARADOTE:

- If you suffer from asthma or have a history of chest tightness.
- If you are using medicine to treat convulsions and / or epilepsy such as phenytoin, phenobarbital, primidone, rifampicin or carbamazepine.

- If you regularly drink a lot of alcohol.

- If you suffer from malnutrition for example if you have anorexia or AIDS.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or healthcare professional for advice before receiving PARADOTE

PARADOTE should not be administered to you if you are pregnant, might be pregnant or if you are breastfeeding. Please consult your doctor if you are unsure.

Driving and using machinery

Driving and using machinery should only be performed once the effect of PARADOTE on you is known.

Using other medicines with PARADOTE

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

There are no known interactions with PARADOTE.

4. HOW PARADOTE WILL BE ADMINISTERED

Do not share medicines prescribed for you with any other person. You will not be expected to give yourself PARADOTE. It will be given to you by a person who is qualified to do so.

PARADOTE is usually given by a doctor or nurse who will dilute the medicine with 5 % dextrose, or 0,9 % sodium chloride, or 0,3 % potassium chloride with 5 % glucose, or 0,3 % potassium chloride with 0,9 % sodium chloride and then inject it slowly into a vein.

PARADOTE is for single use only. Any unused portion of the solution/diluted solution should be discarded.

Administration should commence within 3 hours after dilution.

If more PARADOTE is administered to you than stated or if a dose is missed:

Since a healthcare professional will administer PARADOTE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

5. POSSIBLE SIDE EFFECTS OF PARADOTE

PARADOTE can have side effects. Not all side effects reported for PARADOTE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while PARADOTE is administered to you, please consult your doctor, pharmacist or other health care professional for advice.

If you experience any of the following side-effects tell your doctor or healthcare provider immediately:

Less frequent side-effects:

- Allergic-type reactions including troubled breathing, skin rash and intense itching.

The following side-effects have been reported but the frequency is unknown:

- low blood pressure or high blood pressure
- stopping of heart beat
- reddening of the face, sweating
- nausea and vomiting
- fainting
- muscle pain
- convulsions
- blurred vision.

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

6. STORING AND DISPOSING OF PARADOTE

Store at or below 25 °C.

Protect from light.

Store the ampoule in the outer carton until required for use.

The ampoules are for single use only; discard any unused portion.

Administration should commence within 3 hours after dilution.

Do not freeze.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Do not use after the expiry date printed on the outer carton.

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

7. PRESENTATION OF PARADOTE

Clear, colourless Type I glass ampoules containing 200 mg acetylcysteine per ml. Packs of 10 x 10 ml ampoules per outer carton.

8. IDENTIFICATION OF PARADOTE

A clear, colourless solution, free from visible particulate matter, for administration into a vein.

9. REGISTRATION NUMBER

44/32.16/0329

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Equity Pharmaceuticals (Pty) Ltd

100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive,

Irene, Pretoria

Tel. +27 (0)12 345 1593

11. DATE OF PUBLICATION:

Date of Registration: 20 June 2013

Date of Revision: 23 January 2015