1. WHAT HYALURONIDASE IS AND WHAT IT IS USED FOR

The name of your medicine is Hyaluronidase 1500 I.U. Powder for Solution for Injection or Infusion. The active ingredient in Hyaluronidase 1500 I.U. Powder for Solution for Injection or Infusion is hyaluronidase. Hyaluronidase is an enzyme, a natural substance that activates processes in the body. It is used to temporarily break down the natural barriers in the body tissues so that Injections or fluids injected under the skin or into muscles are more easily spread and absorbed.

Hyaluronidase is also used to enable excess fluids and blood in the tissues to be more easily reabsorbed.

2. BEFORE YOU ARE GIVEN HYALURONIDASE

You should not be given Hyaluronidase:

- if you are known to be allergic to hyaluronidase
- to reduce the swelling of bites or stings
- at sites where infection or malignancy (cancerous growth) is present
- directly onto the front of the eye
- if you are in premature labour for which there is no explanation.

Hyaluronidase should not be administered by Intravenous Injection. If you have any doubts about whether this medicine should be administered then talk to your doctor or nurse before it is given to you.

Pregnancy and breast-feeding

You should let your doctor know if you are pregnant, wish to become pregnant, or are breast-feeding before it is given to you.

Driving and using machines

Hyaluronidase has not been reported to affect ability to drive or operate machines.

HOW HYALURONIDASE SHOULD BE GIVEN

- The usual dose for Hyaluronidase 1500 I.U. is 1500 International Units (iu).
- Hyaluronidase for injection is dissolved in water for injections, normal saline or the solution to be injected.
- Your doctor or nurse will give the injection either into a muscle (intramuscular) or under the skin (subcutaneous).
- For an injection given continuously under the skin (subcutaneous infusion), the injection is injected into the infusion tubing.

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of Proprietary Medicinal Product
Hyaluronidase 1500 I.U. Powder for Solution for Injection or Infusion.

2. Qualitative and Quantitative Composition
Each ampoule contains 1500 international units of Hyaluronidase.

3. Pharmaceutical Form
A white, sterile freeze-dried powder for solution for injection or infusion.

4. Clinical Particulars
4.1 Therapeutic Indications
Hyaluronidase can be used to enhance permeation of subcutaneous or intramuscular injections, local anaesthetics and subcutaneous infusions and to promote resorption of excess fluids and blood in the tissues.

4.3 Contraindications
Hyaluronidase should not be administered by Intravenous Injection.

5. Interactions with Other Medicaments products and Other Forms of Interaction
Hyaluronidase can be used to enhance permeation of subcutaneous or intramuscular injections, local anaesthetics and subcutaneous infusions and to promote resorption of excess fluids and blood in the tissues.

6. Further information

7. How to store

8. Further information
Your doctor will decide the dose and route of administration that is best for you. If you do not understand what you are being given, or are in any doubt, ask your doctor or nurse.

If you think you have been given too much Hyaluronidase
Your doctor will decide which dose is best for you. If you think too much medicine has been given to you contact your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hyaluronidase may cause side-effects in some patients. If you think you have any side-effects, talk to your doctor or nurse. They may stop or change the treatment without telling you to stop taking the medicine:

- Very rarely, severe allergic reactions to Hyaluronidase may occur with difficulty breathing, rapid pulse and profuse sweating. If you develop any of these symptoms, contact your doctor or nurse immediately.
- Hyaluronidase has on rare occasions caused allergic reactions (rash, itching, swelling around the eyes) or soreness, bleeding or bruising at the injection site.
- Local swelling may occur when Hyaluronidase is used with subcutaneous infusions.
- If you experience any side-effects or feel that the medicine is affecting you badly tell your doctor or nurse immediately.

5. HOW TO STORE HYALURONIDASE

Keep out of the reach and sight of children
- Hyaluronidase should not be stored above 25°C. Store the ampoules in the package environment.
- Hyaluronidase should not be given if the powder shows signs of discolouration (it should be white).
- Hyaluronidase should not be used after the expiry date on the label. The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Hyaluronidase looks like and contents of the pack
Hyaluronidase is a sterile, freeze-dried powder in 1 ml neutral glass ampoule, containing 1500 international units of the active ingredient.

The registered pack size is 10 x 1 ml glass ampoules.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Leaflet prepared: February 2014

4.6 Pregnancy and Lactation
It is not known whether the drug enters breast milk although it is unlikely to harm the breast-fed infant. Caution should be exercised in administering it to nursing mothers.

There is no evidence on the drug’s safety in human pregnancy nor is there evidence from animal work that it is free from hazard. Avoid use in pregnancy unless there is no safer alternative.

4.7 Effects on Ability to Drive and to Use Machines
None known.

4.8 Undesirable Effects

Oedema has been reported in association with hypodermoclysis. Allergic reactions have included rare reports of periarticular oedema occurring with the use of hyaluronidase in conjunction with local anaesthetics in ophthalmology. Severe allergic reactions including anaphylaxis have been reported rarely. Local irritation, infection, bleeding and bruising occur rarely.

4.9 Overdose

No cases of overdose appear to have been reported.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties
- Hyaluronidase is an enzyme that has a temporary and reversible depolymerising effect on tissue.

5.2 Pharmacokinetic Properties

Not applicable

5.3 Preclinical Safety Data

There are no additional pre-clinical data of relevance to the prescriber.

6. Pharmaceutical Properties

6.1 List of Excipients

None.

6.2 Incompatibilities

Physical incompatibility has been reported with heparin and adrenaline, although in clinical practice very low concentrations of adrenaline are combined with hyaluronidase without problems. Furosemide, the benzodiazepines and phenytoin have been found to practice very low concentrations of adrenaline are combined with hyaluronidase without problems.

6.3 Shelf Life

Unopened: 3 years.

Once opened use immediately and discard any unused contents.

6.4 Special Precautions for Storage

Do not store above 25°C.

6.5 Nature and Contents of Container

1ml neutral glass ampoule containing a plug of white freeze-dried powder.

Pack size: 10 ampoules.

6.6 Instructions for Use/Handling

The solution should be used immediately after preparation. The appearance of the solution is clear and not more than faintly yellow. For detailed instructions on preparation and administration, see section 4.2.

For single use only. Discard any unused contents.

For detailed instructions on preparation and administration, see section 4.2.