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SOLUTIONS

HYNIDASE® 1500iu (English Alternative) Product Specifications

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Hyaluronidase 1500 I.U. Powder for Solution for Injection or Infusion

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again while you are receiving your treatment.
- If you have any further questions, please ask your doctor or nurse.
- This medicine has been prescribed for you. The contents of your ampoule of Hyaluronidase should not be shared with other patients.

In this leaflet:

1. What Hyaluronidase is and what it is used for
2. Before you are given Hyaluronidase
3. How Hyaluronidase should be given
4. Possible side-effects
5. How to store Hyaluronidase
6. Further information

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 muscle 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.

Hyaluronidase should not be used to enhance the absorption and dispersion of dopamine and/or alpha agonist drugs. If you are taking dopamine or clonidine, or any other alpha agonist drug, please tell your doctor or nurse before you are given this medicine.

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 Hyaluronidase is administered.

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

3. HOW HYALURONIDASE SHIOULD BE GIVEN

- The usual dose for Hyaluronidase 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.

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.

If you think you have missed a dose
If you think that an injection has been missed, speak to you doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hyaluronidase may cause side-effects in some patients.

- 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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

Ireland:
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;
Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie

Malta:
ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt; e-mail: postlicensing.medicinesauthority@gov.mt

By reporting side effects you can help provide more information on the safety of this medicine.

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 container in which they were dispensed.
- The injection must be used immediately after preparation. Any portion of the contents not used at once should be discarded.
- 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 1ml glass ampoules.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland
Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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