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

Pregnancy and breast-feeding

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

Hyalase® is also used to enable excess fluids and blood in the tissues so that injections or fluids injected under the skin into muscle are more easily spread and absorbed.

This medicine has been prescribed for you. The contents of your ampoule of Hyalase® should not be shared with other patients.

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

3. BEFORE YOU ARE GIVEN HYALASE®

You should not be given Hyalase®:
• if you are known to be allergic to hyaluronidase
• if you are taking hyaluronidase or another enzyme
• 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.

Hyalase® should not be administered by Intravenous Injection.

Hyalase® can be used to enhance permeation of subcutaneous or intramuscular injections, local anaesthetics and subcutaneous infusions and to reduce the swelling of blisters or sores.

Hyalase® can 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.

Possible side-effects

• increased sensitivity to local anesthetics
• transitory flushing and redness

5. EFFECTS ON ABILITY TO DRIVE AND TO USE MACHINES

There is no evidence on the drug’s safety in human pregnancy nor is there evidence that it will affect the baby if used in breast milk although it is unlikely to harm the breast-fed infant. Caution should be exercised in administering it to nursing mothers.

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If you have any further questions, please ask your doctor or nurse.

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4. POSSIBLE SIDE EFFECTS

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

• Very rarely, severe allergic reactions to Hyalase® may occur, with difficulty breathing, rapid pulse and profuse sweating. If you develop any of these symptoms, contact your doctor or nurse immediately.

• Hyalase® has on rare occasions caused allergic reactions (itch, itching, swelling around the eyes or soreness, bleeding or bruising at the injection site).

• Local swelling may occur when Hyalase® is used with subcutaneous injections.

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:

United Kingdom: Yellow Card Scheme
Website: http://www.mhra.gov.uk/yellowcard
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 HYALASE®

Keep out of the sight and reach of children

• Hyalase® should not be stored above 25°C. Store the ampoules in the package container in which they were dispensed.

• The injection mixture must be used immediately after preparation. Any portion of the contents not used at once should be discarded.

• Hyalase® should not be given if the powder shows signs of discoloration (it should be white).

• Hyalase® 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 Hyalase® looks like and contents of the pack

Hyalase® is a sterile, freeze-dried powder in 1 ml neutral glass ampoule, containing 1500 international units of the active ingredient (hyaluronidase).

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

Other formats
To listen to or request a copy of this information in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only)

Please be ready to give the following information:

Product Name Reference Number
Hyalase® for Injection/Infusion 1500iu/ml PL 28381/0013

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK
Manufacturer:
CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Leaflet prepared: December 2014

4.8 Undesirable Effects
Oedema has been reported in association with hypodermoclysis. Allergic reactions have included rare reports of periorbital oedema occurring with the use of hyaluronidase in conjunction with local anaesthetics in ophthalmology. Severe allergic reactions (anaphylaxis) have been reported rarely. Local irritation, injection, bleeding and bruising occur rarely.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the beneficial/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

United Kingdom: Yellow Card Scheme
Website: http://www.mhra.gov.uk/yellowcard
Website: www.medicinesauthority.gov.mt; e-mail: postlicensing.medicinesauthority@gov.mt

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 the polysaccharide hyaluronic acid, which is present in the intercellular matrix of connective 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. Pharmacetical 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 in conjunction with local anaesthetics in ophthalmology. Furosemide, the benzodiazepines and phenytoin have been found to be incompatible with hyaluronidase.

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.

7. Marketing Authorisation Holder
Wockhardt UK Ltd
Ash Road North
Wrexham
LL13 9UF

8. Marketing Authorisation Number
UK PL 28381/0013
Malta MA 154/01701

9. Date of First Authorisation/Renewal of Authorisation
April 2008

10. Date of Revision of Text

194205-5