SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF PROPRIETARY MEDICINAL PRODUCT

Hyalase® powder for solution for injection

2. Qualitative and Quantitative Composition

Each ampoule contains 1500 international units of Hyaluronidase.

For excipients see section 6.1.

3. PHARMACEUTICAL FORM

A white, sterile freeze-dried powder for solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Hyalase® 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.

4.2 Posology and Method of Administration

Adults, children and the elderly:

With subcutaneous infusion (hypodermoclysis): 1500iu of Hyalase® dissolved in 1ml of water for injections or normal saline injected into the site, before the infusion is set up, or injected into the tubing of the infusion set, about 2cm back from the needle, at the start of the infusion. 1500iu is sufficient for administration of 500-1000ml of most fluids. Refer to Section 4.4 for information on solutions for hypodermoclysis. Care should be taken in young children and the elderly to control the speed and total volume of fluid administered and to avoid over-hydration, especially in renal impairment.

With subcutaneous or intramuscular injections: 1500iu of Hyalase® dissolved directly in the solution to be injected.

With local anaesthetics: 1500iu Hyalase® is mixed with the quantity of local anaesthetic solution to be used.

In ophthalmology, 15iu of Hyalase® per ml is recommended.

Extravasation: Where dispersal rather than localisation is indicated, 1500iu of Hyalase® in 1ml water for injections or normal saline infiltrated into the affected area as soon as possible after the extravasation is noted.

Haematoma: 1500iu of Hyalase® dissolved in 1ml water for injections or normal saline infiltrated into the affected area.

Immediately before use dissolve the freeze-dried powder in approximately 1 ml of water for injections or directly in the solution with which Hyalase® is to be combined.

4.3 Contraindications

Hypersensitivity to the active ingredient hyaluronidase.

Not to be used for intravenous injections.

Not to be used to reduce the swelling of bites or stings or at sites where infection or malignancy is present.

Not to be used for anaesthetic procedures in cases of unexplained premature labour.

4.4 Special Warnings and Precautions for Use

Do not apply directly to the cornea.

Hyalase® should not be used to enhance the absorption and dispersion of dopamine and/or alpha agonist drugs.

Solutions for subcutaneous administration should be isotonic with extracellular fluid. Hyalase® is physically compatible with the commonly used infusion fluids. Use in hypodermoclysis has been reported with 0.9% sodium chloride, 0.18% sodium chloride with 4% glucose, 0.45% sodium chloride with 2.5% glucose and 5% glucose.

Potassium 34mmol/litre has been administered by hypodermoclysis in isotonic glucose or saline with 1500 I.U/litre hyaluronidase.

Electrolyte-free fluids are less preferable than those containing electrolytes and should not be given too rapidly. Hyalase® has also been mixed with morphine, diamorphine, hydromorphone, chlorpromazine, metoclopramide, promazine, dexamethasone, local anaesthetics and adrenaline (see 6.2. Incompatibilities).

4.5 interactions with Other Medicaments and Other Forms of Interaction

None stated.

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 periorbital 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.

Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

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. PHARMACEUTICAL PARTICULARS

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 be incompatible with hyaluronidase.

6.3 Shelf Life

The expiry date of the product is indicated on the packaging materials.

Once opened use immediately and discard any unused contents.

6.4 Special Precautions for Storage

Store below 25°C.

6.5 Nature and Contents of Container

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

Pack size: 10 or 100 ampoules.

6.6 Special precautions for disposal

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. LICENSE HOLDER

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8. MANUFACTURER

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9. REGISTRATION NUMBER: 128.29.29170

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