

## **Consumer Medicine Information (CMI) summary**

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

# 1. Why am I given HYALASE?

HYALASE contains the active ingredient hyaluronidase. HYALASE is used as an aid in different medical conditions to allow injected substances to be rapidly dispersed and absorbed.

For more information, see Section 1. Why am I given HYALASE? in the full CMI.

# 2. What should I know before I am given HYALASE?

Do not use if you have ever had an allergic reaction to hyaluronidase or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given HYALASE? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with HYALASE and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

# 4. How HYALASE is given?

- Your doctor will decide what dose you will receive. This depends on the medical situation for which HYALASE has been prescribed for you
- HYALASE is given as an injection either into a muscle (intramuscular) or under the skin (subcutaneous). For subcutaneous
  infusion (an injection given continuously under the skin), the injection is injected into the infusion tubing

More instructions can be found in Section 4. How HYALASE is given? in the full CMI.

# 5. What should I know while using HYALASE?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using HYALASE.</li> <li>Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving HYALASE</li> </ul>
Things you should not do	Do not receive HYALASE to treat any other complaints unless your doctor tells you to.
Driving or using machines	The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration
Drinking alcohol	Using alcohol with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with alcohol
Looking after your medicine	HYALASE will be stored in the pharmacy or on the ward. It is kept where the temperature stays below 25°C

For more information, see Section 5. What should I know while using HYALASE? in the full CMI.

## 6. Are there any side effects?

All medicines can have side effects, most of them are minor and temporary. However, some side effects may need medical attention. Serious side effects are allergic reactions such as rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing. Less serious side effects are injection site reactions and/or blurred or decreased vision, restricted eye movements, swelling or fluid in the eye when used in eye surgery.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.



Active ingredient: Hyaluronidase

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using HYALASE. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using HYALASE.

#### Where to find information in this leaflet:

- 1. Why am I given HYALASE?
- 2. What should I know before I am given HYALASE?
- 3. What if I am taking other medicines?
- 4. How HYALASE is given?
- 5. What should I know while using HYALASE?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I given HYALASE?

**HYALASE** contains the active ingredient hyaluronidase. HYALASE is an enzyme and acts to make the tissue between cells more permeable. This allows injected substances to be rapidly dispersed and absorbed.

HYALASE is used in a number of medical conditions. It can be used:

- as an aid during the subcutaneous injection of saline or other solutions
- with anaesthetic agents (agents that cause loss of feeling) during childbirth
- as an aid in prevention of bleeding after childbirth
- as an aid in local anaesthesia involving the eye
- as an aid in local anaesthesia for fractures
- during administration of substances used while taking X-rays

# 2. What should I know before I am given HYALASE?

#### Warnings

## Do not use HYALASE if:

- you are allergic to hyaluronidase, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

You should not receive HYALASE to reduce the swelling of bites or stings or at sites where infection or cancer is present.

## Check with your doctor if you:

- have any other medical conditions such as being allergic to any other medicines or any other substances such as foods, preservatives or dyes
- take any medicines for any other condition
- If you are not sure whether you should receive HYALASE, talk to your doctor or pharmacist.

Your doctor may have prescribed HYALASE for another reason. Ask your doctor if you have any questions about why HYALASE has been prescribed for you.

There is no evidence that HYALASE is addictive.

This medicine is only available with a doctor's prescription

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Like most medicines, HYALASE is not recommended to be used during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor or pharmacist will discuss the possible risks and benefits of using HYALASE during breastfeeding.

# 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with HYALASE and affect how it works.

HYALASE should not be used with the following medicines:

- Adrenaline, a medicine used for the treatment of serious shock or allergic reaction
- Furosemide, a medicine used for the treatment of high blood pressure and oedema
- Heparin, a medicine used to thin your blood
- Phenytoin, a medicine used for seizures.

HYALASE may enhance the adverse events associated with coadministered medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect HYALASE.

# 4. How HYALASE is given?

## How much is given

- Your doctor will decide what dose you will receive. This depends on the medical situation for which HYALASE has been prescribed for you
- Ask your doctor if you want to know more about the dose of HYALASE you receive.

### How long is it given

Your doctor will tell you how long you will be given HYALASE.

#### How is HYALASE given

 HYALASE should only be administered by trained professionals, with appropriate handling, in a hospital or clinic environment

 HYALASE is given as an injection either into a muscle (intramuscular) or under the skin (subcutaneous). For subcutaneous infusion (an injection given continuously under the skin), the injection is injected into the infusion tubing

#### If you use too much HYALASE

As HYALASE is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given HYALASE or if you think that you have been given too much HYALASE, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- · contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using HYALASE?

#### Things you should do

If you are about to be started on any new medicine tell your doctor, dentist or pharmacist that you are receiving HYALASE.

If you plan to have surgery, tell your doctor or dentist that you are receiving HYALASE.

## Call your doctor straight away if you:

do not feel well while you are receiving HYALASE

Remind any doctor, dentist or pharmacist you visit that you are taking HYALASE.

#### Things you should not do

- Do not receive HYALASE to treat any other complaints unless your doctor tells you to.
- Do not self-administer HYALASE.

#### Driving or using machines

Be careful before you drive or use any machines or tools until you know how HYALASE affects you.

## **Drinking alcohol**

Using alcohol with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with alcohol.

#### Looking after your medicine

HYALASE will be stored in the pharmacy or on the ward.
 It is kept where the temperature stays below 25°C.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving HYALASE.

Ask your doctor or pharmacist to answer any questions you may have.

#### Less serious side effects

Less serious side effects	What to do
When used in eye surgery the following may occur:  Blurred or decreased vision, restricted eye movements, swelling or fluid in the eye The following may occur at the injection site:	Speak to your doctor if you have any of these less serious side effects and they worry you.
<ul> <li>Swelling of skin</li> <li>Local irritation</li> <li>Infection</li> <li>bleeding</li> <li>bruising</li> </ul>	

#### Serious side effects

Serious side effects	What to do
Allergic reactions:	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

## 7. Product details

This medicine is only available with a doctor's prescription.

#### What HYALASE contains

Active ingredient	hyaluronidase
(main ingredient)	
Other ingredients	sodium hydroxide

(inactive	
ingredients)	

Do not take this medicine if you are allergic to any of these ingredients.

## What HYALASE looks like

HYALASE is supplied in clear glass ampoules which contain a white or pale yellowish white freeze-dried plug and are available in packs of 5 ampoules (AUST R 27749).

# Who supplies HYALASE

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park, NSW 2113

Toll Free Number (medical information): 1800 818 806

Email: medinfo.australia@sanofi.com

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