

Core CMI for Intra-nasal Corticosteroids (*text in italics is instructional for the CMI writer only*)

[Medicine name][®] (*If you want to include phonetic spelling, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary*).

Generic name

Consumer Medicine Information

Date of Dispensing

Consumer Name

Pharmacist Name

Consumer Address

Pharmacist Address

Consumer Address

Pharmacist Address

This Core leaflet covers both prescription and non-prescription intra-nasal corticosteroid products, and therefore must be modified to suit the particular product being written about. Information in the CMI must be consistent with the product's Product Information (PI).

When writing about consumers seeking advice from health professionals, the schedule of the product should be taken into consideration. Thus:

- *S4 products should direct consumers to seek advice from their **doctor or pharmacist**, and*
- *S3/S2 products should direct consumers to seek advice from their **pharmacist or doctor**.*

What is in this leaflet¹

This leaflet answers some common questions about [Medicine name].

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What [Medicine name] is used for

It may be useful to include subheadings for 'allergic rhinitis (hayfever)' and 'nasal polyps'.

The medicine is sprayed into the nose to help prevent and treat allergic rhinitis (hayfever and other allergies)².

This indication will vary dependent on the product's approved indication, e.g. prevention and/or treatment; seasonal allergic rhinitis or allergic rhinitis, etc.

Hayfever is an inflammation or swelling of the nose lining (which may cause blockage, runny nose, itching and/or sneezing).

You may have symptoms only during spring or summer. This type of allergy is generally due to various pollens. Some people may experience symptoms all year round. This is usually caused by house dust mites, pets or moulds.

The medicine contains (*insert name of active ingredient*). This belongs to a family of medicines called corticosteroids, which are used to help reduce inflammation.

S4 medicines:

The medicine is also used to treat (or used as part of the treatment for) nasal polyps².

A nasal polyp is excess tissue that grows in the sinuses and nose.

S4 medicines:

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

S3/S2 medicines:

Ask your pharmacist if you have any questions about why this medicine has been recommended for you.

This medicine is/is not addictive.

S4 medicines:

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

S3/S2 medicines:

This medicine is available from pharmacists without a prescription.

Before you use [Medicine name]

When you must not use it

Include all Contraindications that appear in the PI (examples below)

¹ Depending on the length of the CMI, consider using a table of contents (see Second Edition of the Usability Guidelines)

² Depending on the product's approved indications

Core CMI for Intra-nasal Corticosteroids *(text in italics is instructional for the CMI writer only)*

Do not use the medicine if:

1 You have an allergy to:

- any medicine containing (*active ingredient*) or any other corticosteroid medicines (*such as medicines of the same class or with a similar structure, as per the PI*).
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath;
- wheezing or difficulty breathing;
- rash.
- (add any other specific reactions listed in the PI)*.

2 You have frequent nose bleeds.

Your condition may cause nose bleeds and still require treatment. Discuss with your doctor if you have any concerns.

3 Any other contraindications as per PI.

S4 medicines:

Do not give this medicine/it to a child under the age of ‘x’ years.

S3/S2 medicines:

Do not give this medicine/it to a child under the age of 12 years.

If necessary, your doctor will prescribe a suitable medicine for children under 12 years of age who have hayfever.

Do not use this medicine/it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your pharmacist or doctor.

Before you start to use it

Include all relevant information from the Precautions section of the PI (examples below). Do not duplicate any information from the previous section.

Tell your doctor/pharmacist³ if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor/pharmacist³ if you have or have had any of the following medical conditions:

- Nasal or sinus infection;
- Recent injury or surgery to your nose;
- Open sores in your nose.
- Other medical conditions as per the PI*

Tell your doctor/pharmacist³ if you are pregnant or plan to become pregnant.

Your doctor/pharmacist³ can discuss with you the risks and benefits involved. *(Place text here if pregnancy is a precaution but not a contraindication).*

Tell your doctor/pharmacist³ if you are breast-feeding.

Your doctor/pharmacist³ can discuss with you the risks and benefits involved. *(Place text here if breast-feeding is a precaution but not a contraindication).*

Any other precautions, as per PI.

If you have not told your doctor/pharmacist³ about any of the above, tell them before you start using the medicine.

Taking other medicines

Tell your doctor/pharmacist³ if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

If applicable, include information on interactions as follows:

Some medicines and this medicine may interfere with each other. These include:

- Other corticosteroid medicines, such as tablets, asthma inhalers, nasal sprays, or eye/nose drops.
- Other medicines as noted in the PI.

³ S4 medicines – tell doctor; S3/S2 medicines – tell pharmacist or doctor

These medicines may be affected by [Medicine name], or may affect how well it works. You may need different amounts of your medicine, or you may need to use a different medicine. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine/it.

How to use [Medicine name]

The following information will be product specific, and consistent with the approved PI. The subheadings and order of information is suggested, but will depend upon the particular product and the amount of information to be given.

It may be useful to include information on starting use before the seasonal triggers start. For example:

Placement of the following statement is optional. It can be positioned here and/or under the ‘How to use it’ sub-heading

Use only in your nose.

To prevent symptoms, start using the medicine

- before the hayfever season, or**
- before coming into contact with something you know will cause your hayfever.**

If you start using this medicine early, it will help reduce the severity of your symptoms.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Include any special device instructions, including reference to a pack insert, priming of the device, sequence of instructions for using the spray, and cleaning of the device.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help³.

Core CMI for Intra-nasal Corticosteroids (*text in italics is instructional for the CMI writer only*)

How to use it

If appropriate, refer to the pack insert leaflet. For example:

Each pack of this medicine contains an instruction leaflet that tells you the correct way to use it. Read the leaflet carefully.

Placement of the following statement is optional. It can be positioned here and/or under the 'How to use it' sub-heading

Use only in your nose.

Gently blow your nose before using it/the medicine .

Where appropriate, include different subheadings for use for:

- *allergic rhinitis (hayfever and other allergies), and*
- *nasal polyps.*

How much to use

For S3/S2 medicines, include advice that the product is only for adults and children 12 years and over.

Include dosage ranges,(including, if applicable, maximum/recommended dosage as per the SUSDP entry for S3/S2 medicines), usual doses for each indication or patient group, dose reduction, etc.

Include different subheadings for use for:

- *allergic rhinitis (hayfever and other allergies), and*
- *nasal polyps.*

Do not exceed the maximum/recommended dose (as applicable).

S3/S2 medicines:

Use a lower dose once your symptoms improve.

S4 medicines:

Your doctor may tell you to reduce the dosage when your symptoms improve.

Use the lowest dose that controls your symptoms

How long to use it

Following are some examples. Choose whichever is appropriate or amend as necessary.

S3/S2 medicines:

See your doctor or pharmacist if your symptoms are not relieved within 7 days.

The medicine only works if it is used on a regular basis.

It generally takes a few days before you notice any improvement in your symptoms.

S3/S2 medicines:

Do not use for more than 6 months without the advice of your doctor or pharmacist.

S4 medicines:

Continue using your medicine for as long as your doctor tells you to.

If you forget to use it

If you miss a dose, use [Medicine name] when the next dose is due.

OR

If it is less than 'x' hours before your next dose, skip the dose you missed. Use it when the next dose is due.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you or someone else accidentally uses too much [Medicine name] on one occasion, there is nothing to worry about.

However, if you use too much of it over a long time (months or years), you may start to get unwanted side effects inside your nose and body.

Discuss any worries you may have about this with you doctor or pharmacist.

Immediately telephone your doctor, or the Poisons Information Centre (telephone 131 126) if you think you or anyone else may have taken too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning.

While you are using [Medicine name]

Things you must do

For S3/S2 medicines:

See your doctor or pharmacist if your symptoms are not relieved within 7 days.

It generally takes a few days before you notice any improvement in your symptoms.

Ask your doctor to examine your nose if you have been using the medicine for several months without a break.

Ask your doctor to examine your nose (*add any other specific tests as per PI*) from time to time to make sure the medicine is working and to prevent unwanted side effects.

For S4 medicines:

Keep all of your doctor's appointments so that your progress can be checked.

Ask your doctor to examine your nose (*add any other specific tests as per PI*) from time to time to make sure the medicine is working and to prevent unwanted side effects.

All presentations may require other appropriate statements. The following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary. Add additional information as per PI.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using this medicine .

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.

If you become pregnant while using this medicine, tell your doctor (*immediately*).

Core CMI for Intra-nasal Corticosteroids (*text in italics is instructional for the CMI writer only*)

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Any other instructions, as per PI.

Things that may be helpful

Add helpful hints relevant to the product. For example, it may be useful to include information on starting use before the seasonal triggers start.

If possible, avoid situations that you know will trigger your symptoms.

To prevent symptoms, start using this medicine

- before the hayfever season, or
- before coming into contact with something you know will cause your hayfever.

If you start using this medicine early, it will help reduce the severity of your symptoms.

Side effects

Suggested general statements to precede the lists of specific side effects:

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine .

This medicine helps most people with (*indication*), but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

(*if there is an increased risk of side effects in the elderly*).

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

The side effects listed for a particular product will depend on the PI and the company's disclosure policy.

Take care to include only those symptoms that the consumer can detect and do something about (refer to glossary of plain-English terms available from Medicines Australia or the ASMI website www.asmi.com.au).

The following possible side effect lists are placed in order of increasing urgency of the behaviour required. You may need to include one or more lists, depending on the PI.

Take care not to duplicate side effects in more than one list so the consumer is not confused about the action that is required.

Add side effects in dot points, grouping like symptoms to keep the lists as short as possible.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- irritated nose or throat
- sneezing
- nose bleeds
- headache
- other common side effects, as per PI.

The above list includes the more common side effects of your medicine. They are usually mild and only last for a short time (*if consistent with the PI*).

Tell your doctor or pharmacist as soon as possible if you notice any of the following:

- frequent nose bleeds
- shortness of breath
- wheezing or difficulty breathing
- rash
- signs or symptoms of a nasal or sinus infection such as fever, pain or swelling, or discoloured nasal discharge (*if applicable*)
- other side effects, as per PI.

The above list includes serious side effects that may require medical attention. Serious side effects are rare (*if consistent with frequencies in the PI*).

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- eye pain or changes in vision (*if applicable*)
- other side effects as per PI.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare (*if consistent with the frequencies in the PI*).

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

(*If some side effects have no symptoms, you can add*) Some of these side effects (*for example, changes in thyroid function, cholesterol level or blood pressure as per PI*) can only be found when your doctor does tests from time to time to check your progress.

After using [Medicine name]

This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

Storage

Keep your spray in a cool dry place where the temperature stays below x°C.

Do not store [Medicine name] or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Core CMI for Intra-nasal Corticosteroids (*text in italics is instructional for the CMI writer only*)**Disposal***Include AUST R number(s)***S4 medicines:****If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.***You may want to include a document code and/or a reference to the approved PI.***S3/S2 medicines:****If you stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

Product description

*This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.***What it looks like***Include colour and markings on container, pack sizes, etc.***Ingredients**

[Medicine name] contains x microgram of (*generic name*) per spray as the active ingredient. It also contains:

- *list excipients in dot points*

Where Australian Food Standard codes exist, these could follow each Australian Approved name.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes (*include any that are appropriate*).

Manufacturer/Distributor/Supplier*(use appropriate heading)*

[Medicine name] is made/distributed/supplied in Australia by:

Include name and address of sponsor

® = Registered Trademark or
™ = Trademark (*if appropriate*)

This leaflet was prepared in
month/year.