

e-Banner	Project: CO-0038221	Document: PPC-0026082	Version: 4
	Site Code: 6200000058430	Operator: SRM58890	Date/Time Created: 21.Apr.2021 13:55 GMT+1

AVAMYS

nasal spray

Fluticasone furoate

What is in this leaflet?

Please read this leaflet carefully before you use AVAMYS. This leaflet answers some common questions about AVAMYS. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking AVAMYS against the risks this medicine could have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What is AVAMYS used for?

AVAMYS is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing, and watery, itchy or red eyes. The effects are usually felt within the first day, although some people will not feel the effects until several days after first taking it.

AVAMYS contains the medicine fluticasone furoate. This medicine belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. They are not 'anabolic steroids' which are the steroids some times misused by athletes.

AVAMYS works to decrease inflammation caused by allergy (rhinitis). Your doctor may have prescribed AVAMYS for another reason. AVAMYS is not addictive.

Before you use AVAMYS

Do not use if:

- You must not use AVAMYS if:
 - You have ever had an allergic reaction to fluticasone furoate or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
 - the expiry date (EXP) printed on the pack has passed.
 - the packaging is torn or shows signs of tampering.

Tell your doctor if:

- You must tell your doctor if:
 - You are allergic to foods, dyes, preservatives or any other medicines.
 - You are taking an antiviral medicine called a protease inhibitor (e.g. ritonavir) or a type of medicine used to treat fungal infections (e.g. ketoconazole).
 - You are taking any other medicines, including medicines you buy without a prescription. This includes inhaled, oral or injected steroids.



- You are breastfeeding, pregnant or trying to become pregnant.

How do I use AVAMYS?

How much to use

Take AVAMYS as directed by your doctor or pharmacist. Don't exceed the recommended dose.

Adults and adolescents 12 years and older:

- The usual starting dose is 2 sprays in each nostril once a day.
- Once symptoms are controlled you may be able to decrease your dose to 1 spray in each nostril once a day.

Children (2 to 11 years):

- The usual starting dose is 1 spray in each nostril once a day.
- If symptoms are severe your doctor may increase the dose to 2 sprays in each nostril once a day until symptoms are under control. It may then be possible for the dose to be reduced to 1 spray in each nostril once a day.

How to use it

See the end of the leaflet for information on HOW TO USE AVAMYS.

Shake well before use

AVAMYS is sprayed into the nose as a fine mist. It has virtually no taste.

AVAMYS is not for use in the eyes.

Use AVAMYS once a day and at the same time each day. This will treat your symptoms throughout the day and night.

How long to use it for

Your doctor will tell you how long to use AVAMYS.

Do not stop using AVAMYS or change the dose without first checking with your doctor.

Use in children

AVAMYS is not recommended for use in children below 2 years of age.

What do I do if I use too much? (Overdose)

Immediately telephone your doctor, if you think you or anyone else may have taken too much AVAMYS, even if there are no signs of discomfort or poisoning. If you are not sure what to do, contact your doctor or pharmacist.

While you are using AVAMYS

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

If you forget to use AVAMYS:

- If you miss a dose, take it when you remember.
- If it is almost time for your next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily. Contact your doctor if you experience a blurred vision or other visual disturbances.

Things you must not do

Do not use AVAMYS in or near the eyes.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use AVAMYS to treat any other complaints unless your doctor says so.

Things to be careful of

Be careful driving or operating machinery until you know how AVAMYS affects you.

AVAMYS is unlikely to affect your ability to drive or use machinery.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking AVAMYS, even if the problem is not listed below.

Like other medicines, AVAMYS can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention. The most commonly reported side-effects are:

- nose bleeds.
- nasal ulceration - which may cause irritation or discomfort in your nose. You may also get streaks of blood when you blow your nose.
- headache.

Uncommon side effects are:

- Pain, burning, irritation, soreness or dryness in the inside of the nose.

Slowing of growth in children has also been observed, however the frequency of this occurring cannot be estimated from the available data.

Tell your doctor immediately if you notice any of the following:

- Wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store AVAMYS?

- Keep this medicine where children cannot reach it, such as in a locked cupboard.
- Store AVAMYS below 30°C.
- Do not refrigerate or freeze.
- Always keep the cap on.
- Do not leave in a car, on a windowsill or in a bathroom.
- Keep AVAMYS in its pack until it is time to use it.
- Return any unused or expired medicine to your pharmacist.
- Store in an upright position
- Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of the month.

- AVAMYS nasal spray should be used within 2 months after first opening.

Product description

What AVAMYS looks like

AVAMYS nasal spray is a white suspension contained in an amber glass bottle, fitted with a pump. The bottle is in an off-white plastic casing with a light blue cap and side-button. The casing has a window for viewing the bottle contents. The bottle contains 120 sprays. Each spray delivers approximately 27.5 micrograms fluticasone furoate.

Ingredients

AVAMYS contains the active ingredient fluticasone furoate. AVAMYS also contains glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride, disodium edetate, and purified water.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Manufactured by:

Glaxo Wellcome S.A.*, Aranda de Duero, Burgos, Spain

Marketing Authorization Holder:

GlaxoSmithKline Australia Pty Ltd*, 1061 Mountain Highway, Boronia VIC 3155, Australia

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Revision date: 05 October 2018 (GDS011 date: 03 April 2018)

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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PharmacoRef n° 7830

Version: 2		Harmony AMS - Artwork Information Panel		gsk	
Manufacturing Site Number: 62000000058430		Manufacturing Site(s): GSK_ARANDA_SPAIN		Technical Drawing (Do NOT include version number): 02-01-XX-273-11	
Product Market Trade Name: Avamys		Approving Market(s): MARKET GROUP-Gulf and Near East		Material Spec: (Do NOT include version number): N/A	
Print Process: N/A		Colour Standard Reference: N/A		Material Type: N/A	
Total Colours & Varnishes: 1					
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				Smallest Text Size: 7.0pt	
				Leading: 8.0pt	
Total Special Finishes: 0					
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				Microtext: N	
Additional Info (1): N/A		Additional Info (2): N/A		Additional Info (3): N/A	
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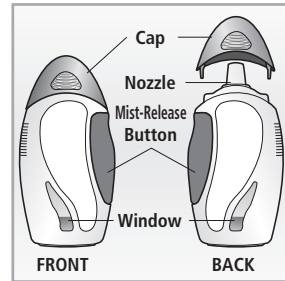
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HOW TO USE AVAMYS

Before using Avamys nasal spray, please read this leaflet carefully and follow these instructions. If you have any further questions on the use of this product, ask your doctor or pharmacist.

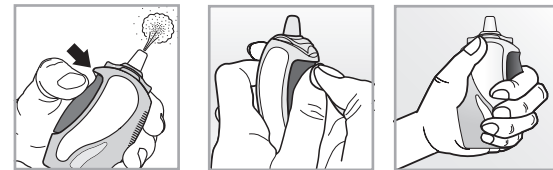
The Nasal Spray



Picture a

- Your medicine comes in a brown glass bottle inside a plastic casing - see (picture a). It will contain 120 sprays.
- A window in the plastic casing allows you to see how much medicine is left. You will not be able to see how much medicine is left for a new 120 spray bottle because the liquid level is above the window.
- The medicine sprays out of the nozzle when the button on the side is pressed firmly all the way in.
- A removable cap protects the nozzle from dust and prevents it from blocking up.

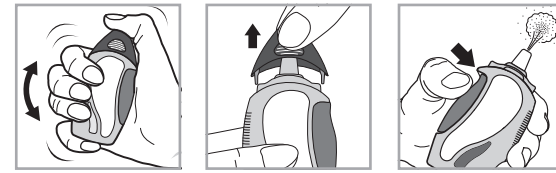
SIX IMPORTANT THINGS YOU NEED TO KNOW ABOUT AVAMYS



- The nasal spray comes in a brown glass bottle. To check how much is left hold the nasal spray upright against a bright light. You will then be able to see the level through the window.
- When you first use the nasal spray, you must prime it - see steps highlighted in "Preparing the Nasal Spray".
- The button on the side must be pressed firmly all the way in, to release a spray through the nozzle - see (picture b).

- If you have difficulty pressing the button with your thumb, you can use two hands - see (picture c) or reverse it to use your four fingers - see (picture d).
- Always keep the cap on the nasal spray when you are not using it. The cap keeps the dust out, seals in the pressure and stops the nozzle from blocking up. When the cap is in place the button on the side can't be pressed accidentally.
- Never use a pin or anything sharp to clear the nozzle. It will damage the nasal spray.

Preparing the Nasal Spray



Picture e

You must prepare the nasal spray:

- Before you use it for the first time.
 - If you have left the cap off for 5 days.
 - If the device doesn't seem to be working.
 - If the nasal spray has not been used for 30 days or more.
- Preparing the nasal spray helps to make sure you always get the full dose of medicine. Follow these steps:

- With the cap on, shake the nasal spray vigorously for about 10 seconds before every use - see (picture e). This is important as Avamys is very thick and becomes more liquid when you shake it well. It will only spray when it becomes liquid.
- Remove the cap by gently squeezing the sides of the cap with your thumb and forefinger and pulling it straight off - see (picture f).
- Hold the nasal spray upright and point the nozzle away from you.
- Press the button firmly all the way in. Do this at least 6 times to release a fine spray into the air - see (picture g).
- The nasal spray is now ready for use. If you have just followed the steps to prepare the nasal spray, you can proceed directly to step 3 of "Using the Nasal Spray".

Using the Nasal Spray



Picture h

- Shake the nasal spray vigorously for about 10 seconds - see picture e.
- Remove the cap.
- Blow your nose to clear your nostrils, and then tilt your head forward a little bit.
- Hold the nasal spray upright and carefully place the nozzle in one of your nostrils - see (picture h).
- Point the end of the nozzle toward the outside of your nose, away from the center ridge of your nose. This helps direct the medicine to the right part of your nose.
- As you breathe in through your nose, press the button once firmly all the way in - see (picture i).
- Be careful not to get any spray in your eyes. If you do, rinse your eyes with water.
- Take the nozzle out and breathe out through your mouth.
- Repeat steps 4 to 8 for your other nostril.
- If your doctor has told you to take 2 sprays per nostril repeat steps 4 to 9.
- Replace the cap on the nasal spray.

Cleaning the Nasal Spray



After each use:

- Wipe the nozzle and the inside of the cap - see (pictures j and k). Don't use water to do this. Wipe with a clean, dry tissue.
- Never use a pin or anything sharp on the nozzle.
- Always replace the cap once you have finished to keep out dust, seal in the pressure and stop the nozzle from blocking up.

If the nasal spray does not seem to be working:

- Check you still have medicine left. Look at the level through the window. If the level is very low there may not be enough left to work the nasal spray.
- Check the nasal spray for damage.
- If you think the nozzle may be blocked, don't use a pin or anything sharp to clear it.
- Try to reset it by following the instructions under "Preparing the Nasal Spray".
- If it is still not working, or if it produces anything other than a fine mist (such as a jet of liquid), or if you feel any discomfort using the spray, return it to your pharmacist.

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كيف تستخدم بخاخ الأنف

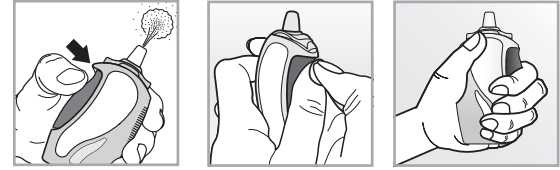
قبل استخدام أفاميس بخاخ الأنف، يرجى قراءة هذه النشرة جيدا وإتبع هذه التعليمات. إذا لديك أي إستفسار عن إستعمال هذا الدواء، إسأل طبيبك أو الصيدلي.
بخاخ الأنف



الصورة أ

- يأتي دواوك في قارورة من زجاج مغلفة بهيكل بلاستيكي -انظر (الصورة أ).
- يحتوي بخاخ الأنف على ١٢٠ رشة.
- تسمح لك النافذة الموجودة في الهيكل البلاستيكي من رؤية كمية الدواء المتبقية. ولن تتمكن من رؤية كمية الدواء المتبقية في الزجاج التي تحتوي على ١٢٠ رشة عندما تكون جديدة، لأن مستوى السائل أعلى من النافذة.
- يُرش الدواء خارجا من الفوهة عندما تضغط على الزر الموجود على الجانب بإحكام إلى الداخل تماما.
- يحمي الغطاء القابل للإزالة، الفوهة من الغبار ويمنعها من الانسداد.

سنة أثمان مهمة يجب عليك معرفتها حول دواء "أفاميس".

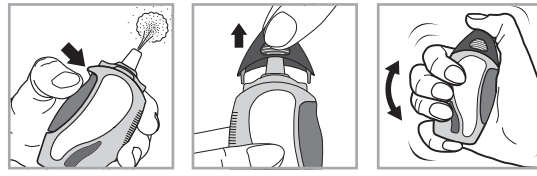


- **الصورة ب**
- يأتي بخاخ الأنف في قارورة زجاجية بنية اللون. للتحقق من كمية الدواء المتبقية، أمسك بخاخ الأنف في وضع مستقيم، في اتجاه الضوء الساطع. ستتمكن بعدا، من رؤية مستوى الدواء من خلال النافذة.
- عند استخدام بخاخ الأنف لأول مرة، يجب عليك تهيئة - راجع الخطوات الموضحة في "تحضير بخاخ الأنف".
- يجب الضغط على الزر الموجود على الجانب بإحكام إلى الداخل تماما، لإطلاق الرشة من خلال فوهة البخاخ -انظر الصورة ب.

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- إذا واجهت صعوبة في الضغط على الزر بإبهامك، فيمكنك استخدام يديك -انظر الصورة ج أو اعكس الاتجاه لاستخدام أصابعك الأربعة - انظر الصورة د.
- احرص دائما على وضع الغطاء الخاص ببخاخ الأنف، إذا لم تكن بصدد استخدامه.
- يحافظ الغطاء على الغبار بعيدا، ويحكم الغلق بالضغط ويمنع فوهة البخاخ من الانسداد.
- عندما يكون الغطاء في مكانه، لا يمكن الضغط على الزر الموجود على الجانب عن طريق الخطأ.
- لا تستخدم أبدا ديوسا أو أي شيء حاد لتنظيف الفوهة. سوف يتلف بخاخ الأنف.

تحضير بخاخ الأنف



الصورة هـ الصورة و الصورة ز

يجب عليك تحضير بخاخ الأنف:

- قبل أن تستخدمه للمرة الأولى.
- إذا كنت قد تركت البخاخ بدون غطاء لمدة خمسة أيام.
- إذا بدا لك أن الجهاز لا يعمل.
- إذا لم تستخدم بخاخ الأنف خلال ثلاثين يوما أو أكثر.
- يساعد تحضير بخاخ الأنف، على التأكد من حصولك دائما على الجرعة الكاملة من الدواء.

اتبع الخطوات التالية:

- مع وضع الغطاء، رَج بخاخ الأنف بقوة لمدة ١٠ ثوان تقريبا قبل كل استخدام -انظر (الصورة هـ). هذا الأمر مهم، لأن دواء "أفاميس" كثيف جدا ويصبح أكثر سيولة عندما ترجه جيدا. سوف تتمكن من رشه فقط عندما يصبح سائلا.
- أزل الغطاء من خلال الضغط بلطف على جانبي الغطاء بإبهامك والسبابة وسحبه مباشرة -انظر (الصورة و).
- أمسك بخاخ الأنف في وضع مستقيم ووجه الفوهة بعيدا عنك.
- اضغط على الزر بإحكام إلى الداخل تماما. أفل هذا ٦ مرات على الأقل لإطلاق رذاذ ناعم في الهواء -انظر (الصورة ز).
- بخاخ الأنف جاهز للاستعمال الآن. إذا كنت قد اتبعت للخطوات تحضير بخاخ الأنف، فيمكنك الانتقال مباشرة إلى الخطوة رقم ٣ من "استخدام بخاخ الأنف".

استخدام بخاخ الأنف



الصورة ح الصورة ط الصورة ظ

- استخدم بخاخ الأنف بقوة لمدة ١٠ ثوان -انظر الصورة هـ.
- بعد نفاث أنفك لتنظيف فتحتي الأنف، أمل رأسك للأمام قليلا.
- أمسك بخاخ الأنف في وضع مستقيم وضع الفوهة بحذر في إحدى فتحتي الأنف -انظر (الصورة ح).
- وجه طرف فوهة البخاخ نحو الجانب الخارجي من أنفك، بعيدا عن منتصف قصبة أنفك. سيساعد هذا الأمر في توجيه الدواء إلى الجزء المناسب من أنفك.
- بينما تأخذ شهيقا من خلال أنفك، اضغط على الزر مرة واحدة بإحكام إلى الداخل تماما -انظر (الصورة ط).
- احرص على عدم دخول أي رذاذ في عينيك. إذا حدث هذا الأمر، اشطف عينيك بالماء.
- أخرج فوهة البخاخ من أنفك، وأخرج الزفير من خلال فمك.
- كرر الخطوات من ٤ إلى ٨ مع فتحة الأنف الأخرى.
- إذا طلب منك طبيبك أن تأخذ رشتين في فتحة الأنف الواحدة، كرر الخطوات من ٤ إلى ٩.
- أعد وضع الغطاء على بخاخ الأنف.

تنظيف بخاخ الأنف



الصورة ي الصورة ك

عقب كل استخدام:

- امسح فوهة البخاخ والمنطقة داخل الغطاء -انظر (الصورتين ي و ك). لا تستخدم الماء لفعل هذا الأمر. استخدم قطعة قماش نظيفة، وجافة للمسح.
- لا تستخدم أبدا ديوسا أو أي شيء حاد في فوهة البخاخ.
- أعد وضع الغطاء دائما بمجرد الانتهاء من تنظيف الغبار، وأحكم الغلق

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