

Package Leaflet: Information for the patient

SANCUSO 3.1 mg/24 hours transdermal patch granisetron

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SANCUSO is and what it is used for
2. What you need to know before you use SANCUSO
3. How to use SANCUSO
4. Possible side effects
5. How to store SANCUSO
6. Contents of the pack and other information

1. What SANCUSO is and what it is used for

The active substance in SANCUSO is granisetron, which belongs to a group of medicines called antiemetics and antinauseants.

SANCUSO is a transdermal (skin) patch used to prevent nausea (feeling sick) and vomiting (being sick) in adults receiving chemotherapy treatments (medicines to treat cancer) lasting 3 to 5 days and who have difficulty swallowing tablets (for example due to soreness, dryness or inflammation of the mouth or throat).

You must talk to a doctor if you do not feel better or if you feel worse after the first day of chemotherapy.

2. What you need to know before you use SANCUSO

Do not use SANCUSO:

- if you are allergic to granisetron or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to any other anti-sickness medicines whose name ends in “setron” e.g. ondansetron.

Warnings and precautions

Tell your doctor or nurse before using this treatment if any of the following applies to you:

- if you have been told you have a heart disorder or disease
- if you have pain in your stomach or your stomach is swollen
- if you have problems with your kidneys or liver.

This medicine may not work as well and/or may affect your skin if exposed to direct sunlight or the light from sunlamps or tanning beds. It is important to do the following:

- while you wear the transdermal patch, keep it covered with clothing if you will be in sunlight or near a sunlamp, including tanning beds
- keep the skin where this medicine was applied covered for another 10 days after the transdermal patch is taken off to protect from exposure to direct sunlight.

It is not known how activities such as swimming, strenuous exercise or using a sauna or whirlpool, may affect this medicine. Avoid these activities while wearing this transdermal patch. You can continue to shower and wash normally while wearing the transdermal patch.

External heat, for example from hot water bottles or heat pads, should be avoided on the area of the transdermal patch.

Children and adolescents

This medicine should not be used by children or adolescents under 18 years.

Other medicines and SANCUSO

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. SANCUSO can affect the way some medicines work. Also, some other medicines can affect the way SANCUSO works. In particular, tell your doctor or nurse if you are taking the following medicines:

- Paracetamol, used to treat pain.
- Phenobarbital, used to treat epilepsy.
- Ketoconazole, used to treat fungal infections.
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram.
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.
- Buprenorphine, Opioids or other serotonergic medicines.

Pregnancy and breast-feeding

Do not use this medicine if you are pregnant unless your doctor has specifically recommended it.

Stop breast-feeding while wearing the patch.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines

SANCUSO has no or negligible effect on your ability to drive or use any machines.

3. How to use SANCUSO

Always use this medicine exactly as your doctor has told you. Check with your doctor or nurse if you are not sure.

The recommended dose is one single transdermal patch. The medicine in the transdermal patch passes gradually through your skin into your body and, therefore, the patch is applied 1 to 2 days (24 to 48 hours) before the start of chemotherapy treatment.

This medicine is for transdermal use. This medicine delivers the active substance slowly and constantly through your skin and into your blood stream for the duration that you are wearing the transdermal patch.

Things to remember when using the transdermal patch

- Do not keep or store the transdermal patch outside the sealed sachet.
- Do not cut the transdermal patch into smaller pieces.
- Use only one transdermal patch at a time.
- When you remove the transdermal patch, check your skin and tell your doctor if you notice a serious skin reaction (if your skin is very red, itchy or you notice any blisters).
- The transdermal patch may be affected by direct sunlight or exposure to sunlamps. While you are wearing the transdermal patch you must keep it covered, e.g. under clothing, if there is a risk of exposure to sunlight or sunlamps. Continue to keep the application site covered for a further 10 days after removing the transdermal patch.
- Contact with water during bathing or showering will not change the way SANCUSO works.
- However, the transdermal patch may become partially unstuck. Try to avoid wearing the transdermal patch in water for long periods of time.
- There is no information on the effect on the transdermal patch of activities such as strenuous exercise or the use of sauna or whirlpools; therefore, you should avoid these activities while wearing this transdermal patch.
- You should avoid external heat (for example hot water bottles or heat pads) on the area of the transdermal patch.

When to apply and remove the transdermal patch

Do not remove the transdermal patch from the sachet until you are ready to use it. Apply a transdermal patch at least 1 day (24 hours) before you are scheduled to have chemotherapy treatment. The transdermal patch may be applied up to a maximum of 2 days (48 hours) before chemotherapy. Wear the transdermal patch all the time during your chemotherapy. The transdermal patch can be worn for up to 7 days depending on the duration of your chemotherapy treatment. Remove the transdermal patch at least 1 day (24 hours) after completing your chemotherapy.

Where to apply the transdermal patch

Put the transdermal patch on a clean, dry, healthy area of skin on the outside part of your upper arm. If your arms are not suitable areas to apply the transdermal patch your doctor may ask you to put it on your abdomen. The area you choose should not be oily, recently shaved or have any skin problems such as being injured (cut or scraped) or irritated (redness or a rash). Do not put SANCUSO on areas that have been treated with creams, oils, lotions, powders or other skin products that could keep the transdermal patch from sticking well to your skin.

How to apply the transdermal patch

1. Remove a sachet from the box and tear it open using the slit provided. Each sachet contains one transdermal patch stuck onto a rigid plastic film.
2. Take the transdermal patch out of the sachet.



3. The sticky side of the transdermal patch is covered by a two-piece rigid plastic film. Bend the transdermal patch in the middle and remove one half of the rigid plastic film. Be careful not to stick the transdermal patch to itself and avoid touching the sticky side of the transdermal patch.
4. While holding the remaining half of the rigid plastic film, apply the transdermal patch to the skin on the outside part of your upper arm.

5. Remove the second half of the rigid plastic film and press the whole transdermal patch firmly in place with your fingers and smooth down. Press firmly making sure there is good contact with the skin, especially around the edges.
6. Wash your hands after applying the transdermal patch.
7. Keep the transdermal patch in place for the whole time you are having chemotherapy.
8. Do not re-use the transdermal patch after removal, see below for instructions on transdermal patch removal and disposal (see section 5).

After removing the transdermal patch

1. The used transdermal patch will still contain some granisetron and should be disposed of immediately as described in section 5.
2. After removing the transdermal patch you may find some sticky material is left on your skin. Gently wash the area with soap and water to remove it. Alcohol or other dissolving liquids such as nail polish remover may cause skin irritation and should not be used.
3. Wash your hands.
4. You may see mild redness on the skin where the transdermal patch is removed. This redness should go away over time. If it does not, tell your doctor.

If the transdermal patch becomes unstuck

If the transdermal patch starts to become unstuck, the same transdermal patch may be secured to the same area of skin. If required, use surgical bandages or medical adhesive tape to keep the transdermal patch in place. If the transdermal patch is lost or becomes damaged go back to your doctor.

If you use more SANCUSO than you should

If you use more SANCUSO than you should, simply remove the extra patch(es) and contact your doctor.

If you forget to use SANCUSO

It is important to use this medicinal product as instructed by your doctor to prevent you feeling sick or being sick following your chemotherapy. If you have forgotten to apply your transdermal patch at the right time, apply it as soon as you remember, and tell your doctor as soon as possible before your chemotherapy treatment.

If you stop using SANCUSO

It is important to use this medicine during the whole length of your chemotherapy (up to 7 days) to prevent you feeling sick or being sick following your chemotherapy. Talk to your doctor if you want to remove the patch before the end of your chemotherapy treatment course (up to 7 days).

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you are being treated with chemotherapy that is moderately or highly capable of making you feel sick, you may still be sick despite treatment with anti-sickness medicine, including this medicine.

Tell your doctor immediately if you develop constipation or if your stomach becomes painful or swollen. Constipation is a common side effect and may affect up to 1 in 10 people.

Remove the transdermal patch and tell your doctor if you notice:

- signs and symptoms of a condition called Serotonin Syndrome, which can be serious and in some cases life threatening. These may include changes in blood pressure (which could make you feel dizzy or have a headache), fast heartbeat, blurred vision (which may be due to dilation of the pupil of the eye), sweating, increased bowel movements/noises, shivering, tremor, muscle twitching or jerking, and overactive reflexes. You may also have a high or

very high temperature (fever), feel agitated or confused, have stiff muscles, and notice that you are talking faster. How many people will get Serotonin Syndrome is not known (cannot be estimated from available data)

- a serious skin reaction (if your skin is very red, itchy or you notice any blisters). Skin reactions at the site of application, such as irritation, itching or redness are uncommon and may affect up to 1 in 100 people.

Other possible side effects:

Uncommon side effects are:

- headache, a feeling of “spinning” even when you are standing still (vertigo)
- decreased appetite, weight loss
- flushing (or redness)
- feeling sick (nausea), retching, dry mouth
- pain in your joints
- swelling due to water retention (oedema)
- changes in liver function tests (if you are having blood tests, tell the doctor or nurse that you have been given SANCUSO).

Rare side effects (may affect up to 1 in 1,000 people) are:

- abnormal muscle movements (such as shaking, muscle rigidity and muscle contractions).

Side effects with a frequency not known (cannot be estimated from available data):

- allergic skin reactions. The signs may include red, raised itchy bumps

Other possible side effects associated with granisetron products (frequency not known):

- Allergic reactions including urticaria (itchy, red, raised skin rash) and anaphalaxis (a serious allergic reaction which may include sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching)
- Difficulty sleeping/disturbed sleep
- Excessive sleepiness
- Prolonged QT interval in the ECG (changes to the heart rate trace (ECG) indicating a heart rhythm disorder)
- Constipation
- Diarrhoea
- Lack of energy/weakness /Loss of strength

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme - Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SANCUSO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and the sachet after ‘EXP’. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Used transdermal patches still contain active ingredients, which may be harmful to others. Fold the used transdermal patch in half with the sticky side inwards and dispose of it safely, out of the reach of children. Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What SANCUSO contains

- The active substance is granisetron. Each 52 cm² transdermal patch contains 34.3 mg of granisetron, releasing 3.1 mg of granisetron in 24 hours.
- The other ingredients are:
- Transdermal patch adhesive: acrylate-vinylacetate copolymer
- Backing layer: polyester
- Rigid plastic film: siliconised polyester

What SANCUSO looks like and contents of the pack

SANCUSO is a thin, clear, rectangular-shaped transdermal patch with rounded corners, stuck onto a rigid plastic film. The transdermal patch is contained in a sachet. Each carton contains one transdermal patch.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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