Tuxxalib 5 mg/ml powder for dispersion for infusion
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Package leaflet: Information for the user

Tuxxalib 5 mg/ml powder for dispersion for infusion

paclitaxel

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.

The full name of this medicine is Tuxxalib 5 mg/ml powder for dispersion for infusion. It will be referred to as Tuxxalib throughout this leaflet.

What is in this leaflet:

1. What Tuxxalib is and what it is used for

What this medicine is

This medicine contains, as its active substance, paclitaxel attached to the human protein albumin, in the form of tiny particles known as nanoparticles. Paclitaxel belongs to a group of medicines called "taxanes" used for cancer treatment.
- Paclitaxel is the part of the medicine that affects the cancer, it works by stopping cancer cells from dividing – this means that they die.
  Albumin is the part of the medicine that helps paclitaxel dissolve in the blood and get across the walls of the blood vessels into the tumour. This means that other chemicals that can cause side effects that can be life threatening are not needed. Such side effects occur far less with Tuxxalib.

What this medicine is used for

This medicine is used to treat the following types of cancer:

Breast Cancer
- Breast cancer which has spread to other parts of the body (this is called "metastatic" breast cancer).
- This medicine is used in metastatic breast cancer when at least one other therapy has been tried but has not worked and you are unsuitable for treatments containing a group of medicines called "anthracyclines".
- People with metastatic breast cancer who received this medicine where another therapy had failed, were more likely to experience a reduction in tumour size, and lived longer than people who took an alternative therapy.

Pancreatic cancer
- This medicine is used together with a medicine called gemcitabine if you have metastatic cancer of the pancreas. People with metastatic pancreatic cancer (pancreatic cancer that has spread to other parts of the body) who received this medicine with gemcitabine in a clinical trial lived longer than people who had only received gemcitabine.

Lung cancer
- This medicine is also used together with a medicine called carboplatin if you have the most common type of lung cancer, called "non-small cell lung cancer".
- This medicine is used in non-small cell lung cancer where surgery or radiotherapy would not be suitable to treat the disease.

2. What you need to know before you are given Tuxxalib

Do not use this medicine

- if you are allergic (hypersensitive) to paclitaxel or any of the other ingredients of this medicine (listed in section 6);
- if you are breast-feeding;
- if you have a low white blood cell count (baseline neutrophil counts <1,500 cells/mm3 - your doctor will advise you on this).

Warnings and precautions

Talk to your doctor or nurse before using this medicine
- if you have poor kidney function;
- if you have severe liver problems;
- if you have heart problems.

Talk to your doctor or nurse if you experience any of these conditions whilst being treated with this medicine, your doctor may wish to stop treatment or reduce the dose:
- if you experience any abnormal bruising, bleeding, or signs of infections such as a sore throat or a fever;
- if you experience numbness, tingling, pricking sensations, sensitivity to touch, or muscle weakness;
- if you experience breathing problems, like shortness of breath or dry cough.

Children and adolescents

This medicine is only for adults and should not be taken by children and adolescents aged below 18 years.

Other medicines and Tuxxalib

Tell your doctor if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Tuxxalib can affect the way some other medicines work. Also, some other medicines can affect the way this medicine works.

Take care and speak to your doctor when taking this medicine at the same time as any of the following:
- medicines for treating infections (i.e. antibiotics such erythromycin, rifampicin, etc.; ask your doctor, nurse or pharmacist if you are unsure whether the medicine you are taking is an antibiotic), including medicines for treating fungal infections (e.g. ketoconazole)
- medicines used to help you stabilize your mood also sometimes referred to as anti-depressants (e.g. fluoxetine)
- medicines used to treat seizures (epilepsy) (e.g. carbamazepine, phenytoin)
- medicines used to help you lower blood lipid levels (e.g. gemfibrozil)
- medicine used for heartburn or stomach ulcers (e.g. cimetidine)
- medicines used to treat HIV and AIDS (e.g. ritonavir, saquinavir, indinavir, nelfinavir, efavirenz, nevirapine)
- a medicine called clopidogrel used to prevent blood clots.

Pregnancy, breast-feeding and fertility

Tuxxalib may cause serious birth defects and should therefore not be used if you are pregnant. Your doctor will arrange a pregnancy test before starting treatment with this medicine.

Women of childbearing age should use effective contraception during and up to 1 month after receiving treatment with this medicine.

Do not breast feed when taking this medicine as it is not known if the active ingredient paclitaxel passes into the mother's milk.

Male patients are advised to use effective contraception and to avoid fathering a child during and up to six months after treatment and should seek advice on conservation of sperm prior to treatment because of the possibility of irreversible infertility due to therapy with this medicine.

Ask your doctor for advice before taking this medicine.

Driving and using machines

Some people may feel tired or dizzy after being given this medicine. If this happens to you, do not drive or use any tools or machines.
If you are given other medicines as part of your treatment, you should ask your doctor for advice on driving and using machines.

This medicine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ml reconstituted solution, that is to say essentially 'sodium free'.

3. How to use Tuxxalib

This medicine will be given to you by a doctor or nurse into a vein from an intravenous drip. The dose you receive is based on your body surface area and blood test results. The usual dose is for breast cancer is 260 mg/m^2 of body surface area given over a 30 minute period. The usual dose for advanced pancreatic cancer is 125 mg/m^2 of body surface area given over a 30 minute period. The usual dose for non-small cell lung cancer is 100 mg/m^2 of body surface area given over a 30 minute period.

How often will you receive this medicine?

For treatment of metastatic breast cancer, this medicine is usually given once every three weeks (on day 1 of a 21-day cycle).

For treatment of advanced pancreatic cancer, this medicine is given on days 1, 8 and 15 of each 28-day treatment cycle with gemcitabine being given immediately Tuxxalib.

For treatment of non-small cell lung cancer this medicine is given once every week (i.e. on days 1, 8 and 15 of a 21-day cycle), with carboplatin being given once every three weeks (i.e. only on day 1 of each 21-day cycle), immediately after the Tuxxalib dose has been given.

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 everyone gets them.

The **very common** side effects may affect more than 1 in 10 people:
- Loss of hair (the majority of cases of hair loss happened less than one month after starting treatment with this medicine. When it happens, hair loss is pronounced (over 50%) in the majority of patients)
- Rash
- Abnormal decrease in the number of types of white blood cells (neutrophils, lymphocytes or leukocytes) in the blood
- Deficiency of red blood cells
- Reduction in the number of platelets in the blood
- Effect on peripheral nerves (pain, numbness, tingling or loss of feeling)
- Pain in a joint or joints
- Pain in the muscles
- Nausea, diarrhoea, constipation, sore mouth, loss of appetite
- Vomiting
- Weakness and tiredness, fever
- Dehydration, taste disturbance, weight loss
- Low levels of potassium in the blood
- Depression, sleep problems
- Headache
- Chills
- Difficulty in breathing
- Dizziness
- Swelling of mucosal and soft tissues
- Increased liver function tests
- Pain in extremities
- Cough
- Abdominal pain
- Nose bleeds

The **common** side effects may affect up to 1 in 10 people:
- Itching, dry skin, nail disorder
- Infection, fever with decrease in the number of a type of white blood cell (neutrophils) in the blood, flushing, thrush, severe infection in your blood which may be caused by reduced white blood cells
- Reduction in all blood cell counts
- Chest or throat pain
- Indigestion, abdominal discomfort
- Stuffy nose
- Pain in back, bone pain
- Diminished muscular coordination or difficulty in reading, increased or decreased tears, loss of eyelashes
- Changes in heart rate or rhythm, heart failure
- Decreased or increased blood pressure
- Redness or swelling at the site where the needle entered the body
- Anxiety
- Infection in the lungs
- Infection in the urinary tract
- Obstruction in the gut, inflammation of the large bowel, inflammation of the bile duct
- Acute kidney failure
- Increased bilirubin in the blood
- Coughing up blood
- Dry mouth, difficulty in swallowing
- Muscle weakness
- Blurred vision

The **uncommon** side effects may affect up to 1 in 100 people:
- Increased weight, increased lactate dehydrogenase in the blood, decreased kidney function, increased blood sugar, increased phosphorus in the blood
- Decreased or lack of reflexes, involuntary movements, pain along a nerve, fainting, dizziness when standing up, shaking, facial nerve paralysis
- Irritated eyes, painful eyes, red eyes, itchy eyes, double vision, reduced vision, or seeing flashing lights, blurred vision due to swelling of the retina (cystoid macular oedema)
- Ear pain, ringing in your ears
- Coughing with phlegm, shortness of breath when walking or climbing stairs, runny nose, or dry nose, decreased breath sounds, water on the lung, loss of voice, blood clot in the lung, dry throat
- Gas, stomach cramps, painful or sore gums, rectal bleeding
- Painful urination, frequent urination, blood in the urine, inability to hold your urine
- Fingernail pain, fingernail discomfort, loss of fingernails, hives, skin pain, red skin from sunlight, skin discolouration, increased sweating, night sweats, white areas on the skin, sores, swollen face
- Decreased phosphorus in the blood, fluid retention, low albumin in the blood, increased thirst, decreased calcium in the blood, decreased sugar in the blood, decreased sodium in the blood
- Pain and swelling in the nose, skin infections, infection due to catheter line
- Bruising
- Pain at site of tumour, death of the tumour
- Decreased blood pressure when standing up, coldness in your hands and feet
- Difficulty walking, swelling
- Allergic reaction
- Decreased liver function, increased size of liver
- Pain in the breast
- Restlessness
- Small bleedings in your skin due to blood clots
- A condition involving destruction of red blood cells and acute kidney failure

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Medical or healthcare professionals

The following information is intended for medical or healthcare professionals only:

Instructions for use, handling and disposal

Preparation and administration precautions

Tuxxalib is a cytotoxic anticancer medicinal product and, as with other potentially toxic compounds, caution should be exercised in handling this medicine. Gloves, goggles and protective clothing should be used. If this medicine contacts the skin, the skin should be washed immediately and thoroughly with soap and water. If this medicine contacts mucous membranes, the membranes should be flushed thoroughly with water. This medicine should only be prepared and administered by personnel appropriately trained in the handling of cytotoxic agents. Pregnant staff should not handle this medicine.

Given the possibility of extravasation, it is advisable to closely monitor the infusion site for possible infiltration during administration of the medicinal product. Limiting the infusion to 30 minutes, as directed, reduces the likelihood of infusion-related reactions.

Reconstitution of the product and administration

This medicine should be administered under the supervision of a qualified oncologist in units specialised in the administration of cytotoxic agents.

This medicine is supplied as a sterile lyophilised powder for reconstitution before use. After reconstitution, each ml of dispersion contains 5 mg of paclitaxel formulated as albumin bound nanoparticles. Reconstituted Tuxxalib is administered intravenously using an infusion set incorporating a 15 µm filter.

Reconstitution of 100 mg:
Using a sterile syringe, 20 ml of sodium chloride 9 mg/ml (0.9%) solution for infusion should slowly be injected into the 100 mg vial over a minimum of 1 minute.

The solution should be directed onto the inside wall of the vial. The solution should not be injected directly onto the powder as this will result in foaming.

Once the addition is complete, the vial should be allowed to stand for a minimum of 5 minutes to ensure proper wetting of the solid. Then, the vial should gently and slowly be swirled and/or inverted for at least 2 minutes until complete redispersion of any powder occurs. The generation of foam should be avoided. If foaming or clumping occurs, the dispersion should stand for at least 15 minutes until foam subsides.

The reconstituted dispersion should be milky and homogenous without visible precipitates. Some settling of the reconstituted dispersion may occur. If precipitates or settling are visible, the vial should be gently inverted again to ensure complete redispersion prior to use. Inspect the dispersion in the vial for particulate matter. Do not administer the reconstituted dispersion if particulate matter is observed in the vial.

The exact total dosing volume of 5 mg/ml dispersion required for the patient should be calculated and the appropriate amount of reconstituted dispersion should be injected into an empty, sterile, PVC or non-PVC type intravenous bag.

The use of medical devices containing silicone oil as a lubricant (i.e. syringes and IV bags) to reconstitute and administer this medicine may result in the formation of proteinaceous strands.

Administer this medicine using an infusion set incorporating a 15 µm filter to avoid administration of these strands. Use of a 15 µm filter removes strands and does not change the physical or chemical properties of the reconstituted product.

Use of filters with a pore size less than 15 µm may result in blockage of the filter.

The use of specialized DEHP-free solution containers or administration sets is not necessary to prepare or administer this medicine.

Following administration, it is recommended that the intravenous line be flushed with sodium chloride 9 mg/ml (0.9%) solution for injection to ensure administration of the complete dose.

Any unused product or waste material should be disposed of in accordance with local requirements.

Stability

Unopened vials are stable until the date indicated on the package when the vial is kept in the outer carton in order to protect from light. Neither freezing nor refrigeration adversely affects the stability of the product. This medicinal product does not require any special temperature storage conditions.

Stability of the reconstituted dispersion in the vial

Chemical and physical in-use stability has been demonstrated for 24 hours at 2°C-8°C in the original carton, protected from light.

Stability of the reconstituted dispersion in the infusion bag

Chemical and physical in-use stability has been demonstrated for 24 hours at 2°C-8°C followed by 4 hours at 25°C, protected from light.

However, from a microbiological point of view, unless the method of reconstituting and filling of the infusion bags precludes the risks of microbial contamination, the product should be used immediately after reconstitution and filling of the infusion bags.

If not used immediately, in-use storage times and conditions are the responsibility of the user. The total combined storage time of reconstituted medicinal product in the vial and in the infusion bag when refrigerated and protected from light is 24 hours. This may be followed by storage in the infusion bag for 4 hours below 25°C.

The **rare** side effects may affect up to 1 in 1,000 people:
- Skin reaction to another agent or lung inflammation following radiation
- Blood clot
- Very slow pulse, heart attack
- Leaking of drug outside the vein
- A disorder of the electrical conduction system of the heart (atrioventricular block)

The **very rare** side effects may affect up to 1 in 10,000 people:
- Severe inflammation/eruption of the skin and mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis)

Not known side effects (frequency cannot be estimated from the available data):
- Hardening/thickening of the skin (scleroderma).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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 at 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 Tuxxalib

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 carton and the vial after EXP. The expiry date refers to the last day of that month.

Unopened vials: Keep the vial in the outer carton in order to protect from light.

After first reconstitution the dispersion should be used immediately. If not used immediately, the dispersion may be stored in a refrigerator (2°C-8°C) for up to 24 hours in the vial when kept in the outer carton in order to protect it from light.

The reconstituted dispersion in the intravenous drip may be stored in a refrigerator (2°C-8°C) for up to 24 hours protected from light.

The total combined storage time of reconstituted medicinal product in the vial and in the infusion bag when refrigerated and protected from light is 24 hours. This may be followed by storage in the infusion bag for 4 hours below 25°C.

Your doctor or pharmacist is responsible for disposing of any unused medicine correctly.

6. Contents of the pack and further information

What this medicine contains

The active substance is paclitaxel.

Each vial contains 100 mg of paclitaxel formulated as albumin bound nanoparticles.

After reconstitution, each ml of dispersion contains 5 mg of paclitaxel formulated as albumin bound nanoparticles.

The other ingredient is human albumin (containing sodium caprylate and N-acetyl-L-tryptophan).

What this medicine looks like and contents of the pack

Tuxxalib is a white to yellow powder for dispersion for infusion. This medicine is available in glass vials containing 100 mg of paclitaxel formulated as albumin bound nanoparticles.

Each pack contains 1 vial.

Marketing Authorisation Holder

STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

For any information about this medicine, please contact the Marketing Authorisation Holder.

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