

Package leaflet: Information for the user

Soliris 300 mg concentrate for solution for infusion Eculizumab

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, pharmacist 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Soliris is and what it is used for

What is Soliris

Soliris contains the active substance eculizumab and it belongs to a class of medicines called monoclonal antibodies. Eculizumab binds to and inhibits a specific protein in the body that causes inflammation and so prevents your body's systems from attacking and destroying vulnerable blood cells, kidneys, muscles or eye nerves and spinal cord.

What is Soliris used for

Paroxysmal Nocturnal Haemoglobinuria

Soliris is used to treat adults and children patients with a certain type of disease affecting the blood system called Paroxysmal Nocturnal Haemoglobinuria (PNH). In patients with PNH, their red blood cells can be destroyed which can lead to low blood counts (anaemia), tiredness, difficulty in functioning, pain, dark urine, shortness of breath, and blood clots. Eculizumab can block the body's inflammatory response, and its ability to attack and destroy its own vulnerable PNH blood cells.

Atypical Haemolytic Uremic Syndrome

Soliris is also used to treat adults and children patients with a certain type of disease affecting the blood system and kidney called atypical Haemolytic Uremic Syndrome (aHUS). In patients with aHUS, their kidney and blood cells, including platelets, can be inflamed which can lead to low blood counts (thrombocytopenia and anaemia), reduced or lost kidney function, blood clots, tiredness and difficulty in functioning. Eculizumab can block the body's inflammatory response, and its ability to attack and destroy its own vulnerable blood and kidney cells.

Refractory Generalized Myasthenia Gravis

Soliris is also used to treat adult and children patients aged 6 years and above with a certain type of disease affecting the muscles and called generalized Myasthenia Gravis (gMG). In patients with gMG, their muscles can be attacked and damaged by the immune system which can lead to profound muscle weakness, impaired mobility, shortness of breath, extreme fatigue, risk for aspiration, and markedly impaired activities of daily living. Soliris can block the body's inflammatory response, and its ability to

attack and destroy its own muscles to improve muscle contraction, thereby reducing symptoms of the disease and impact of the disease on the activities of daily living. Soliris is specifically indicated for patients who remain symptomatic despite treatment with other existing MG therapies.

Neuromyelitis Optica Spectrum Disorders

Soliris is also used to treat adult patients with a certain type of disease that predominantly affects the eye nerves and the spinal cord called Neuromyelitis Optica Spectrum Disorder (NMOSD). In patients with NMOSD, their eye nerve and spinal cord are attacked and damaged by the immune system which can lead to blindness in one or both eyes, weakness or paralysis in the legs or arms, painful spasms, loss of sensation, and markedly impaired activities of daily living. Soliris can block the body's inflammatory response, and its ability to attack and destroy its own eye nerves and spinal cord, thereby reducing symptoms of the disease and impact of the disease on the activities of daily living.

2. What you need to know before you use Soliris

Do not use Soliris

- If you are allergic to eculizumab, proteins derived from mouse products, other monoclonal antibodies, or any of the other ingredients of this medicine (listed in section 6).
- If you have not been vaccinated against meningococcal infection unless you take antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated.
- If you have a meningococcal infection.

Warnings and precautions

Meningococcal and other *Neisseria* infections alert

Soliris treatment may reduce your natural resistance to infections, especially against certain organisms that cause meningococcal infection (severe infection of the linings of the brain and sepsis) and other *Neisseria* infections including disseminated gonorrhoea.

Consult your doctor before you take Soliris to be sure that you receive vaccination against *Neisseria meningitidis*, an organism that causes meningococcal infection, at least 2 weeks before beginning therapy, or that you take antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated. Ensure that your current meningococcal vaccination is up to date. You should also be aware that vaccination may not prevent this type of infection. In accordance with national recommendations, your doctor might consider that you need supplementary measures to prevent infection.

If you are at risk of gonorrhoea, ask your doctor or pharmacist for advice before using this medicine.

Meningococcal infection symptoms

Because of the importance of rapidly identifying and treating certain types of infection in patients who receive Soliris, you will be provided a card to carry with you, listing specific trigger symptoms. This card is named: "Patient Safety Card".

If you experience any of the following symptoms, you should immediately inform your doctor:

- headache with nausea or vomiting
- headache with a stiff neck or back
- fever
- rash
- confusion
- severe muscle aches combined with flu-like symptoms
- sensitivity to light

Treatment for meningococcal infection while travelling

If you are travelling in a remote region where you are unable to contact your doctor or in which you find yourself temporarily unable to receive medical treatment, your doctor can make arrangements to issue, as a preventive measure, a prescription for an antibiotic to counter *Neisseria meningitidis* that you keep with you. If you experience any of the symptoms amongst those cited above, you should take the antibiotics as prescribed. You should bear in mind that you should see a doctor as soon as possible, even if you feel better after having taken the antibiotics.

Infections

Before starting Soliris, inform your doctor if you have any infections.

Allergic reactions

Soliris contains a protein and proteins can cause allergic reactions in some people.

Children and adolescents

Patients less than 18 years of age must be vaccinated against *Haemophilus influenzae* and pneumococcal infections

Older people

There are no special precautions needed for the treatment of patients aged from 65 years and over.

Other medicines and Soliris

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Pregnancy, breast-feeding, and fertility

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

Women of childbearing potential

The use of effective contraception during treatment and up to 5 months after treatment should be considered in women who are able to get pregnant.

Pregnancy/ Breast-feeding

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

Driving and using machines

Soliris has no or negligible influence on the ability to drive and use machines.

Soliris contains sodium

Once diluted with sodium chloride 9 mg/mL (0.9%) solution for injection, this medicine contains 0.88g sodium (main component of cooking/table salt) in 240 mL at the maximal dose. This is equivalent to 44% of the recommended maximum daily dietary intake of sodium for an adult. You should take this into consideration if you are on a controlled sodium diet.

Once diluted with sodium chloride 4.5 mg/mL (0.45%) solution for injection, this medicine contains 0.67g sodium (main component of cooking/table salt) in 240 mL at the maximal dose. This is equivalent to 33.5% of the recommended maximum daily dietary intake of sodium for an adult. You should take this into consideration if you are on a controlled sodium diet.

Soliris contains polysorbate 80

This medicine contains 6.6 mg of polysorbate 80 in each vial (30mL vial) which is equivalent to 0.66 mg/kg or less at the maximum dose for adult patients and paediatric patients with body weight more than 10 kg and is equivalent to 1.32 mg/kg or less at the maximum dose for paediatric patients with body weight 5 to <10 kg. Polysorbates may cause allergic reactions. Tell your doctor if you/your child has any known allergies.

3. How to use Soliris

At least 2 weeks before you start treatment with Soliris, your doctor will administer a vaccine against meningococcal infection if it was not previously administered or if your vaccination is outdated. If your child is below the age of vaccination or if you are not vaccinated at least 2 weeks before you start treatment with Soliris, your doctor will prescribe antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated.

Your doctor will administer a vaccine to your child aged less than 18 years against *Haemophilus influenzae* and pneumococcal infections according to the national vaccination recommendations for each age group.

Instructions for proper use

The treatment will be given by your doctor or other health care provider by infusing a dilution of the Soliris vial from a drip bag through a tube directly into one of your veins. It is recommended that the beginning of your treatments, called the initial phase, will extend over 4 weeks, followed by a maintenance phase.

If you use this medicine to treat PNH

For adults:

- **Initial Phase:**
Every week for the first four weeks, your doctor will administer an intravenous infusion of diluted Soliris. Each infusion will consist of a dose of 600 mg (2 vials of 30 ml) and will take 25 – 45 minutes (35 minutes ± 10 minutes).
- **Maintenance Phase:**
 - In the fifth week, your doctor will administer an intravenous infusion of diluted Soliris at a dose of 900 mg (3 vials of 30 ml) over a 25 – 45 minute (35 minutes ± 10 minutes) period.
 - After the fifth week, your doctor will administer 900 mg of diluted Soliris every two weeks as a long-term treatment.

If you use this medicine to treat aHUS, refractory gMG or NMOSD

For adults:

- **Initial Phase:**
Every week for the first four weeks, your doctor will administer an intravenous infusion of diluted Soliris. Each infusion will consist of a dose of 900 mg (3 vials of 30 ml) and will take 25 – 45 minutes (35 minutes ± 10 minutes).
- **Maintenance Phase:**
 - In the fifth week, your doctor will administer an intravenous infusion of diluted Soliris at a dose of 1,200 mg (4 vials of 30 ml) over a 25 – 45 minute (35 minutes ± 10 minutes) period.
 - After the fifth week, your doctor will administer 1,200 mg of diluted Soliris every two weeks as a long-term treatment.

Children and adolescents with PNH, aHUS or refractory gMG and who are 40 kg weight and over are treated with the adult dosing.

Children and adolescents with PNH, aHUS or refractory gMG and who are under 40 kg weight require a lower dose based on how much they weigh. Your doctor will calculate this.

For children and adolescents with PNH and aHUS aged less than 18 years:

Body Weight	Initial Phase	Maintenance Phase
30 to <40 kg	600 mg weekly for the first 2 weeks	900 mg at week 3; then 900 mg every 2 weeks
20 to <30 kg	600 mg weekly for the first 2 weeks	600 mg at week 3; then 600 mg every 2 weeks
10 to <20 kg	600 mg single dose at week 1	300 mg at week 2; then 300 mg every 2 weeks
5 to <10 kg	300 mg single dose at week 1	300 mg at week 2; then 300 mg every 3 weeks

Subjects who undergo plasma exchange may receive additional doses of Soliris.

Following each infusion, you will be monitored for about one hour. Your doctor’s instructions should be carefully observed.

If you receive more Soliris than you should

If you suspect that you have been accidentally administered a higher dose of Soliris than prescribed, please contact your doctor for advice.

If you forget an appointment to receive Soliris

If you forget an appointment, please contact your doctor immediately for advice and see section below “If you stop using Soliris”.

If you stop using Soliris for PNH

Interrupting or ending treatment with Soliris may cause your PNH symptoms to come back more severely soon. Your doctor will discuss the possible side effects with you and explain the risks. Your doctor will want to monitor you closely for at least 8 weeks.

The risks of stopping Soliris include an increase in the destruction of your red blood cells, which may cause:

- A significant fall in your red blood cell counts (anaemia),
- Confusion or change in how alert you are,
- Chest pain, or angina,
- An increase in your serum creatinine level (problems with your kidneys), or
- Thrombosis (blood clotting).

If you have any of these symptoms, contact your doctor.

If you stop using Soliris for aHUS

Interrupting or ending treatment with Soliris may cause your aHUS symptoms to come back. Your doctor will discuss the possible side effects with you and explain the risks. Your doctor will want to monitor you closely.

The risks of stopping Soliris include an increase in the inflammation of your platelets, which may cause:

- A significant fall in your platelets (thrombocytopenia),
- A significant rise in destruction of your red blood cells,
- Decreased urination (problems with your kidneys),
- An increase in your serum creatinine level (problems with your kidneys),
- Confusion or change in how alert you are,
- Chest pain, or angina,

- Shortness of breath, or
- Thrombosis (blood clotting).

If you have any of these symptoms, contact your doctor.

If you stop using Soliris for refractory gMG

Interrupting or stopping treatment with Soliris may cause your gMG symptoms to come back. Please speak to your doctor before stopping Soliris. Your doctor will discuss the possible side effects and risks with you. Your doctor will also want to monitor you closely.

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

If you stop using Soliris for NMOSD

Interrupting or stopping treatment with Soliris may cause your NMOSD to worsen and relapse to happen. Please speak to your doctor before stopping Soliris. Your doctor will discuss the possible side effects and risks with you. Your doctor will also want to monitor you closely.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will discuss the possible side effects with you and explain the risks and benefits of Soliris with you prior to treatment.

The most serious side effect was meningococcal sepsis.

If you experience any of the meningococcal infection symptoms (see section 2 Meningococcal and other *Neisseria* infections alert), you should immediately inform your doctor.

If you are not sure what the side effects below are, ask your doctor to explain them to you.

Very common: may affect more than 1 in 10 people: headache.

Common: may affect up to 1 in 10 people:

- infection of the lung (pneumonia), common cold (nasopharyngitis), infection of the urinary system (urinary tract infection),
- low white blood cell count (leukopenia), reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- inability to sleep
- dizziness, high blood pressure
- upper respiratory tract infection, cough, throat pain (oropharyngeal pain), bronchitis, cold sores (herpes simplex)
- diarrhoea, vomiting, nausea, abdominal pain, rash, hair loss (alopecia), itchy skin (pruritus)
- pain in the joints (arms and legs), pain in the limbs (arms and legs)
- fever (pyrexia), feeling tired (fatigue), influenza like illness
- infusion related reaction

Uncommon: may affect up to 1 in 100 people:

- severe infection (meningococcal infection), sepsis, septic shock, viral infection, lower respiratory tract infection, stomach flu (gastrointestinal infection), cystitis
- infection, fungal infection, collection of pus (abscess), type of infection of the skin (cellulitis), influenza, sinusitis, tooth infection (abscess), gum infection

- relatively few platelets in blood (thrombocytopenia), low level of lymphocytes a specific type of white blood cells (lymphopenia), feeling your heartbeat
- serious allergic reaction which causes difficulty in breathing or dizziness (anaphylactic reaction), hypersensitivity
- loss of appetite
- depression, anxiety, mood swings, sleep disorder
- tingling in part of the body (paresthesia), shaking, taste disorders (dysgeusia), fainting
- vision blurred
- ringing in the ears, vertigo
- sudden and rapid development of extremely high blood pressure, low blood pressure, hot flush, vein disorder
- dyspnoea (difficulty breathing), nose bleed, stuffy nose (nasal congestion), throat irritation, runny nose (rhinorrhoea)
- inflammation of the peritoneum (the tissue that lines most of the organs of the abdomen), constipation, stomach discomfort after meals (dyspepsia), abdominal distension
- hives, redness of the skin, dry skin, red or purple spots under the skin, increased sweating, inflammation of the skin
- muscle cramp, muscle aches, back and neck pain, bone pain
- kidney disorder, difficulties or pain when urinating (dysuria), blood in urine
- spontaneous penile erection
- swelling (edema), chest discomfort, feeling of weakness (asthenia), chest pain, infusion site pain, chills
- increase of liver enzymes, decrease of the proportion of blood volume that is occupied by red blood cells, decrease in the protein in red blood cells that carries oxygen

Rare: may affect up to 1 in 1,000 people:

- infection by fungi (*Aspergillus* infection), infection of the joint (arthritis bacterial), *Haemophilus* infection, impetigo, bacterial sexual transmitted disease (gonorrhoea)
- skin tumor (melanoma), bone marrow disorder
- destruction of red blood cells (haemolysis), clumping of cells, abnormal clotting factor, abnormal blood clotting,
- disease with thyroid overactivity (Grave's disease)
- abnormal dreams
- irritation of eye
- bruise
- unusual backflow of food from stomach, gum pain
- yellowing of the skin and/or eyes (jaundice)
- skin color disorder
- spasm of mouth muscle, joint swelling
- menstrual disorder
- abnormal leakage of the infused drug out of the vein, infusion site abnormal sensation, feeling hot

Reporting of side effects

If you get any side effects, talk to your doctor or 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 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 Soliris

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 vial label after “EXP”. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Soliris vials in the original package may be removed from refrigerated storage **for only one single period of up to 3 days**. At the end of this period the product can be put back in the refrigerator.

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

After dilution, the product should be used within 24 hours.

Do not throw away any medicines via wastewater. 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 Soliris contains

- The active substance is eculizumab (300 mg/30 ml in a vial corresponding to 10 mg/ml).
- The other ingredients are:
 - sodium phosphate monobasic
 - sodium phosphate dibasic
 - sodium chloride
 - polysorbate 80 (vegetable origin)Solvent: water for injections
- Soliris contains sodium and polysorbate 80. See section 2.

What Soliris looks like and contents of the pack

Soliris is presented as a concentrate for solution for infusion (30 ml in a vial – pack size of 1).

Soliris is a clear and colorless solution.

Marketing Authorisation Holder

Alexion Europe SAS
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France

Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Instructions for Use for Healthcare Professionals Handling Soliris

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

1- How is Soliris supplied?

Each vial of Soliris contains 300 mg of active ingredient in 30 ml of product solution.

2- Before Administration

Reconstitution and dilution should be performed in accordance with good practices rules, particularly for the respect of asepsis.

Soliris should be prepared for administration by a qualified healthcare professional using aseptic technique.

- Inspect visually Soliris solution for particulate matter and discolouration.
- Withdraw the required amount of Soliris from the vial(s) using a sterile syringe.
- Transfer the recommended dose to an infusion bag.
- Dilute Soliris to a final concentration of 5 mg/ml (initial concentration divided by 2) by adding the appropriate amount of diluent to the infusion bag. For 300 mg doses, use 30 ml of Soliris (10 mg/ml) and add 30 ml of diluent. For 600 mg doses, use 60 ml of Soliris and add 60 ml of diluent. For 900 mg doses, use 90 ml of Soliris and add 90 ml of diluent. For 1,200 mg doses, use 120 ml of Soliris and add 120 ml of diluent. The final volume of a 5 mg/ml diluted Soliris solution is 60 ml for 300 mg doses, 120 ml for 600 mg doses, 180 ml for 900 mg doses or 240 ml for 1,200 mg doses.
- Diluents are Sodium chloride 9 mg/ml (0.9%) solution for injection, Sodium chloride 4.5 mg/ml (0.45%) solution for injection or 5% dextrose in Water.
- Gently agitate the infusion bag containing the diluted Soliris solution to ensure thorough mixing of the medicinal product and diluent.
- The diluted solution should be allowed to warm to room temperature [18°C – 25°C] prior to administration by exposure to ambient air.
- The diluted solution must not be heated in a microwave or with any heat source other than the prevailing room temperature.
- Discard any unused portion left in a vial.
- Diluted solution of Soliris may be stored at 2°C – 8°C for up to 24 hours prior to administration.

3- Administration

- Do not administer Soliris as an intravenous push or bolus injection.
- Soliris should only be administered via intravenous infusion.
- The diluted solution of Soliris should be administered by intravenous infusion over 25 to 45 minutes (35 minutes ± 10 minutes) in adults and 1-4 hours in paediatric patients under 18 years of age via gravity feed, a syringe-type pump, or an infusion pump. It is not necessary to protect the diluted solution of Soliris from light during administration to the patient.

The patient should be monitored for one hour following infusion. If an adverse event occurs during the administration of Soliris, the infusion may be slowed or stopped at the discretion of the physician. If the infusion is slowed, the total infusion time may not exceed two hours in adults and four hours in paediatric patients under 18 years of age.

4- Special Handling and Storage

Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original package in order to protect from light. Soliris vials in the original package may be removed from refrigerated storage **for only one single period of up to 3 days**. At the end of this period the product can be put back in the refrigerator.

Do not use this medicine after the expiry date which is stated on the carton and vial label after 'EXP'. The expiry date refers to the last day of that month.