



PNH PARENT INFORMATION BROCHURE:

Very Important Safety Information
for Children and Infants with
Paroxysmal Nocturnal Haemoglobinuria
(PNH) who are taking Soliris®



This document was last approved in March 2021 by the Israeli Ministry of Health (MOH)


Soliris® — Helping You Manage PNH

Soliris is a medicine to treat a very serious illness called PNH. The illness is not caused by bacteria or a virus, so it is not contagious or spreadable to others. Some medicines, such as Soliris, work by affecting the body's immune system, so they can make your child more susceptible to certain other illnesses. Please review the Very Important Safety Information below.

VERY IMPORTANT SAFETY INFORMATION

Since Soliris blocks a part of the body's immune system, your child's natural resistance to infections may be reduced, especially against certain organisms that cause meningococcal infections, including meningitis and septicaemia, which is also known as blood poisoning or sepsis. Meningococcal infections are extremely dangerous and may become life threatening in less than 4 hours.¹ Provide this pamphlet to any of your child's caregivers to help them identify the signs and symptoms of meningitis. They should seek **IMMEDIATE** medical attention should any sign or symptom appear.

Soliris is administered through infusion—liquid medicine that is put into the body through the vein and should be prepared by a doctor or by someone who is trained to give this medicine. If Soliris causes a reaction, please notify the doctor who gave your child Soliris.

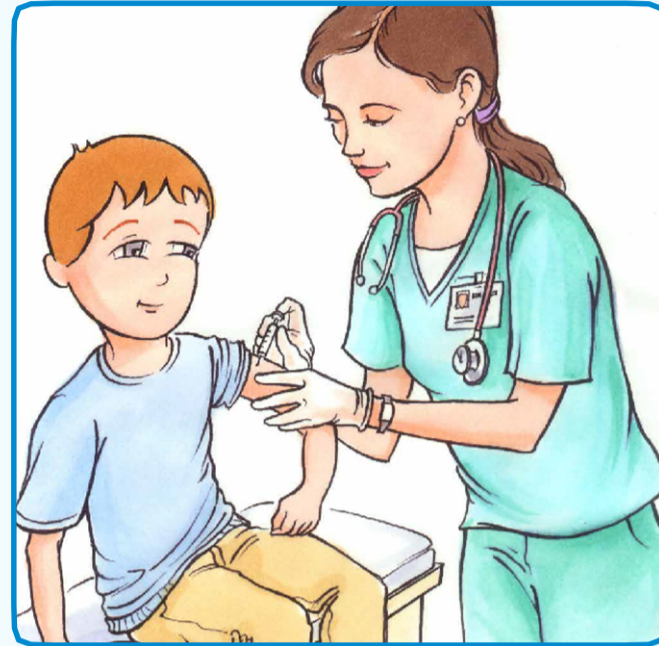


Place photo
of your child
here

Your healthcare professional may give your child a vaccination to decrease the chance of your child getting meningococcal infection. However, vaccination cannot fully protect against the possibility that your child may become infected with meningitis. Your child must be vaccinated against meningococcal infection at least 2 weeks before receiving the first Soliris infusion.

If no vaccine is available for your young child, your child must receive antibiotics throughout the treatment period and until 2 weeks after your child receives a vaccination.

Your child must also be vaccinated against *Haemophilus influenzae* and pneumococcal infections according to your country's recommendations for each age group.

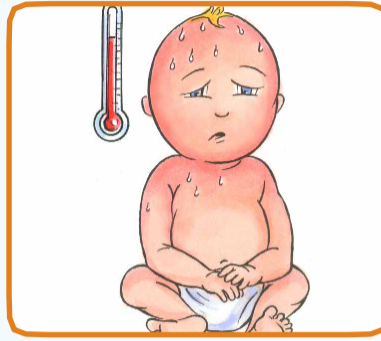


**meningitis can kill in less than 4 hours.¹
Do not wait for a rash to appear because it may not appear.² If ANY sign or symptom should appear, seek medical attention immediately.**

Signs and Symptoms of Meningitis and/or Sepsis, Which Are Life-threatening Infections

Your child is taking Soliris®, which reduces natural defenses against meningitis and sepsis. Meningitis and sepsis are **EXTREMELY DANGEROUS** infections and may quickly become **LIFE THREATENING**. In infants, the signs and symptoms can be different from those often seen in young children. These illustrations can help you identify signs and symptoms that can be seen in infants. For young children, refer to pages 6 and 7.

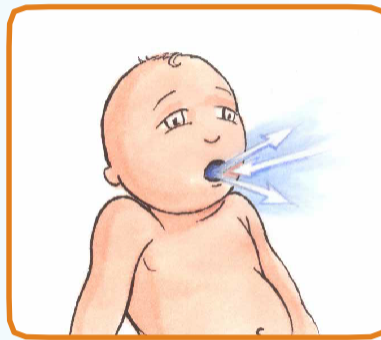
It is very important to seek medical care IMMEDIATELY if you see ANY of the following signs and symptoms.



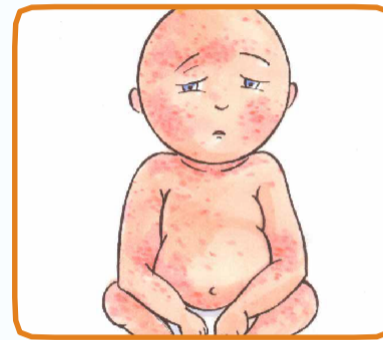
Fever³



Cold hands and/or feet³



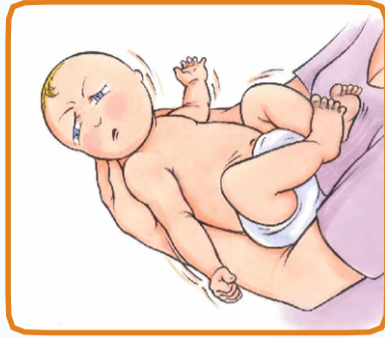
Rapid breathing³



Pale, blotchy skin; spots/rash³



Refusing food and/or vomiting³



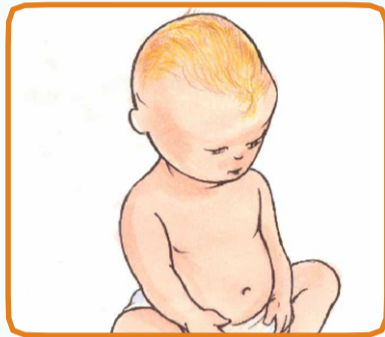
Dislikes being handled³



Drowsy, floppy, unresponsive³



Unusual cry, moaning³

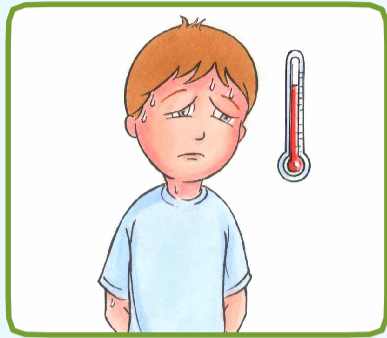


Tenseness or bulging of the usually soft spot on the head³

Not everyone gets all these signs and symptoms of meningitis and sepsis. It is very important to seek medical care **IMMEDIATELY if you see **ANY** of these signs and symptoms.**

Signs and Symptoms of Meningitis and/or Sepsis, Which Are Life-threatening Infections

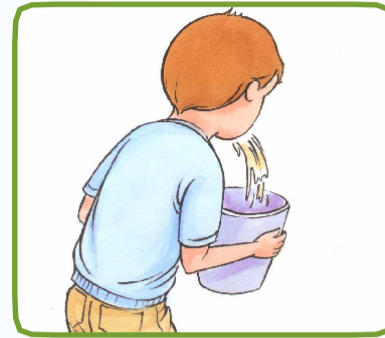
Meningitis and sepsis are extremely dangerous infections and may quickly become life threatening. These illustrations can help you identify signs and symptoms that can be seen in young children. For infants, refer to pages 4 and 5. **It is very important to seek medical care IMMEDIATELY if you see ANY of the following signs and symptoms.**



Fever^{2,4}



Cold hands and/or feet^{2,4}



Vomiting^{2,4}



Stiff neck²

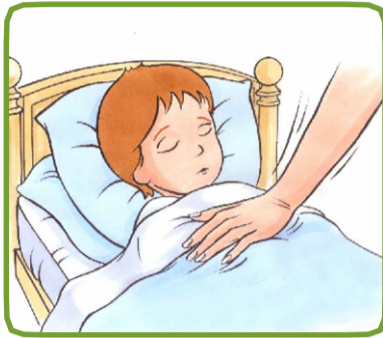


Dislikes bright lights²



Pale, blotchy skin; spots/rash^{2,4}

Not everyone gets all these signs and symptoms of meningitis and sepsis. It is very important to seek medical care **IMMEDIATELY** if you see **ANY** of the following signs and symptoms.



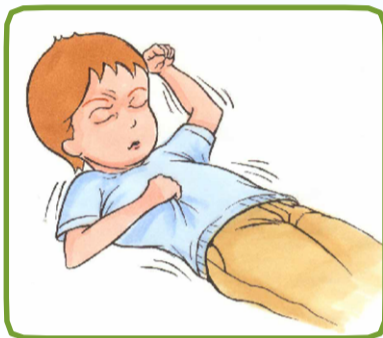
Drowsy, difficult to wake^{2,4}



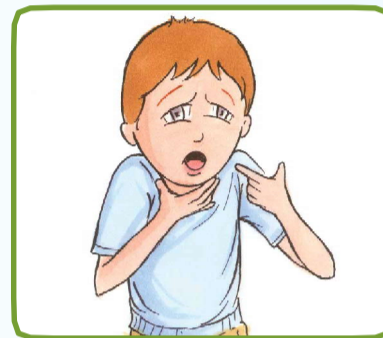
Confusion and irritability^{2,4,5}



Severe headache²



Uncontrollable shaking²



Difficulties breathing^{2,4}



Leg pain⁵

Patient Safety Information Cards

The Patient Safety Information Cards at the end of this brochure contain important safety information that you or anyone responsible for the care of your child should know throughout the duration of your child's Soliris® therapy and beyond. Because Soliris may reduce your child's natural resistance to infections, it is important to recognise the signs and symptoms of infections, including those of meningitis and sepsis. These cards include a list of the signs and symptoms of these infections, so anyone supervising your child can recognise an infection of meningitis and sepsis, and seek **IMMEDIATE** medical attention.

Fill out the cards and give one to anyone responsible for the care of your child (for example, a teacher, babysitter/nanny, daycare center staff). Also, be sure to carry a set with you at all times. Extra copies of this brochure and safety card are available for free by calling 1-800-250-255 or email the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com.



Inform the person watching over your child that these cards should be shown to any healthcare professional involved in your child's treatment, should your child need medical attention.

Very Important Safety Information

Since Soliris blocks a part of the body's immune system, your child's natural resistance to infections may be reduced, especially against certain organisms that cause meningococcal infections, including meningitis and septicaemia, which is also known as blood poisoning or sepsis.

Meningococcal infections are **EXTREMELY DANGEROUS** and may become **LIFE THREATENING** in less than 4 hours.¹ Provide a copy of this pamphlet to all of your child's caregivers to help them identify the signs and symptoms of meningitis and sepsis. They should seek **IMMEDIATE** medical attention should any sign or symptom appear.



For parents/legal guardians of newborns and infants: please be aware that the typical signs and symptoms of headache, fever, neck stiffness, muscle pain, joint pain, rash, and shock may be hard to detect; other signs and symptoms in babies to be aware of include inactivity, vomiting and lack of interest in feeding.

What are the signs and symptoms that should alert me during Soliris treatment?

Vaccination reduces the risk of developing an infection but does not eliminate the risk completely.

You will need to be aware of the signs and symptoms of serious infection and notify your healthcare professional **IMMEDIATELY** if your child has ANY of the following symptoms:

- Fever
- Cold hands and/or feet
- Refusing food and/or vomiting
- Dislikes being handled
- Drowsy, floppy, unresponsive
- Rapid breathing
- Pale, blotchy skin; spots/rash
- unusual cry, moaning
- Tenseness or bulging of the usually soft spot on the head

PATIENT SAFETY INFORMATION CARD

Place photo
of your child here

Important information for supervising individuals

This child is currently being treated with Soliris® and may have reduced natural resistance to infections, especially meningococcal infections, which include meningitis and blood poisoning (also known as sepsis). If you notice that the child has any of the signs and symptoms listed on this card, which could indicate a serious infection, call his or her doctor immediately.

meningitis can kill in less than 4 hours.¹ Do not wait for a rash to appear because it may not appear.² If ANY sign or symptom should appear, seek medical attention immediately.

If you cannot reach the child's doctor, take the child to the Emergency Department immediately and show the staff this card.

Patient name _____

Parent/Guardian contact information _____






















Physician name _____

Physician contact information _____

IMPORTANT SAFETY INFORMATION FOR HEALTHCARE PROFESSIONALS

This patient was prescribed Soliris therapy. Soliris is an antibody that inhibits terminal complement activation. Due to its mechanism of action, the use of Soliris increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*). Before beginning treatment, this patient should have received a meningococcal vaccine, but he or she may still be susceptible to meningococcal infections or other general infections. You should carefully monitor the emergence of early signs of meningococcal infection, evaluate immediately if infection is suspected, and treat with antibiotics if necessary. Some patients have experienced infusion reactions following administration of Soliris. Common general disorders or administration site conditions include chest discomfort, chills, fatigue, asthenia, infusion-related reaction, oedema, and pyrexia. For more information about Soliris, please refer to the Summary of Product Characteristics. In case of safety concerns, call 1-800-250-255 or email the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com.

PATIENT SAFETY INFORMATION CARD

Meningitis and Septicaemia Symptoms: INFANTS		Meningitis and Septicaemia Symptoms: YOUNG CHILDREN	
 Fever ³	 Cold hands and/or feet ³	 Fever ^{2,4}	 Uncontrollable shaking ²
 Refusing food and/or vomiting ³	 Dislikes being handled ³	 Cold hands and/or feet ^{2,4}	 Difficulties breathing ^{2,4}
 Drowsy, floppy, unresponsive ³	 Rapid breathing ³	 Vomiting ^{2,4}	 Leg pain ⁵
 Pale, blotchy skin; spots/rash ³	 Unusual cry, moaning ³	 Drowsy, difficult to wake ^{2,4}	
 Tenseness or bulging of usually soft spot on the head ³		 Confusion and irritability ^{2,4,5}	
		 Severe headache ²	
		 Stiff neck ²	
		 Dislikes bright lights ²	
		 Pale, blotchy skin; spots/rash ^{2,4}	

References: 1. About us. Meningitis Research Foundation website. <http://www.meningitisuk.org/about-us.htm>. Accessed September 30, 2011. 2. Symptoms in young people. Meningitis Research Foundation website. <http://www.meningitis.org/symptoms/young-people>. Accessed June 17, 2011. 3. Meningitis symptoms in babies. Meningitis Research Foundation website. <http://www.meningitis.org/symptoms/babies>. Accessed June 17, 2011. 4. What are meningitis and septicaemia? Meningitis Research Foundation website. <http://www.meningitis.org/disease-info/what-are-meningitis-septicaemia>. Accessed July 6, 2011. 5. Haj-Hassan TA, Thompson MJ, Mayon-White RT, et al. Which early 'red flag' symptoms identify children with meningococcal disease in primary care? *Br J Gen Pract.* 2011;61:171-172.

Please see accompanying Package Leaflet for Soliris, including information regarding meningococcal infections.

Soliris® is a registered trademark of Alexion Pharmaceuticals, Inc. Copyright © 2017, Alexion Pharmaceuticals, Inc. All rights reserved. SolXXX

SOLIRIS[®]
(eculizumab)

For parents/legal guardians:

IF YOUR CHILD SHOWS ANY SIGNS OR SYMPTOMS OF MENINGITIS OR SEPSIS, CONTACT YOUR HEALTHCARE PROFESSIONAL IMMEDIATELY.

If you cannot reach your healthcare professional, seek IMMEDIATE emergency care at an Emergency department and show the staff your Patient Safety Information Card

References: 1. About us. Meningitis Research Foundation website. <http://www.meningitisuk.org/about-us.htm>. Accessed September 30, 2011. 2. Symptoms in young people. Meningitis Research Foundation website. <http://www.meningitis.org/symptoms/young-people>. Accessed June 17, 2011. 3. Meningitis symptoms in babies. Meningitis Research Foundation website. <http://www.meningitis.org/symptoms/babies>. Accessed June 17, 2011. 4. What are meningitis and septicaemia? Meningitis Research Foundation website. <http://www.meningitis.org/disease-info/what-are-meningitis-septicaemia>. Accessed July 6, 2011. 5. Haj-Hassan TA, Thompson MJ, Mayon-White RT, et al. Which early 'red flag' symptoms identify children with meningococcal disease in primary care? *Br J Gen Pract*. 2011;61:171-172.

In case of safety concerns, call 1-800-250-255 or email the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

Please see enclosed Package Leaflet for Soliris® (eculizumab), including information regarding serious meningococcal infections.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to a portal, or by the following link: <https://sideeffects.health.gov.il> and by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com
Tel: 1-800-250-255



92-FEB-2022