PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

INTRALIPID® 20 % Emulsion for intravenous infusion

Purified soybean oil

Contains sugar (as glycerol anhydrous 22,0 g/1 000 mL)

Read all of this leaflet carefully before you are given INTRALIPID 20 %

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What INTRALIPID 20 % is and what it is used for
2. What you need to know before you are given INTRALIPID 20 %
3. How INTRALIPID 20 % will be administered to you
4. Possible side effects
5. How to store INTRALIPID 20 %
6. Contents of the pack and other information

1. What INTRALIPID 20 % is and what it is used for

INTRALIPID 20 % provides energy and fats needed by your body straight into your bloodstream when you cannot eat normally. They are used as part of a balanced intravenous diet, together with proteins, carbohydrates, salts and vitamins. INTRALIPID 20 % is particularly useful following severe injury, burns or in patients with serious infections.

2. What you need to know before you are given INTRALIPID 20 %

INTRALIPID 20 % should not be administered to you:

- if you are hypersensitive (allergic) to egg -, soy- or peanut protein or to soybean oil or any of the other ingredients of INTRALIPID 20 % (listed in section 6).
- if your body is currently in shock (resulting from heavy blood loss or allergic reaction) or if you have problems with fat metabolism.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Take special care with INTRALIPID 20 %:

- if you have problems with your liver, kidneys or pancreas
- if you have high cholesterol
- if you have high blood sugar (diabetes mellitus)
- if you currently have an infection
- if you have thyroid problems.

Your doctor may want to do regular blood tests to make sure your body is using INTRALIPID 20 % correctly.

No other medicines should be added to INTRALIPID 20 % unless it is safe to do so.

Children

Tell your doctor if your baby has jaundice (yellowing of the skin and/or eyes) or lung problems such as pulmonary hypertension. Your doctor may want to do regular blood tests.

Your healthcare provider will ensure that INTRALIPID 20 % is protected from light exposure during administration to babies younger than 2 years.

Other medicines and INTRALIPID 20 %

Always tell your healthcare provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)

Tell your doctor if you are using or taking the following:

- Insulin for the treatment of high blood sugar (diabetes mellitus)
- Heparin for treatment and prevention of blood clots in veins, arteries or lungs
- Warfarin for prevention of blood clots from forming or growing larger in your blood and blood vessels.

INTRALIPID 20 % with food, drink and alcohol

Not applicable

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before you receive INTRALIPID 20 %.

Driving and using machines

No effects on the ability to drive and use machines are to be expected.

It is not always possible to predict to what extent INTRALIPID 20 % may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which INTRALIPID 20 % affects them.

INTRALIPID 20 % contains:

INTRALIPID 20 % contains soybean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reactions have been observed between soybean and peanuts (see “INTRALIPID 20 % should not be administered to you”).

3. How INTRALIPID 20 % will be administered to you

You will not be expected to give yourself INTRALIPID 20 %. It will be given to you by a person who is qualified to do so.

INTRALIPID 20 % is usually given through a vein with other solutions, such as amino acids (proteins), sugars, salts and vitamins.

Dosage

Your doctor will prescribe the appropriate volume of INTRALIPID 20 % to be administered to you.

If you have the impression that the effect of INTRALIPID 20 % is too strong or too weak, tell your doctor or pharmacist.

Method of administration

INTRALIPID 20 % is given slowly by drip through a small plastic tube (a catheter) straight into your bloodstream. An electronic pump may be used to control the speed of your drip.

How often will your medicines be given

INTRALIPID 20 % will usually be given every day until you can start eating again.

Duration of treatment

Your doctor will tell you how long your treatment with INTRALIPID 20 % will last.

If INTRALIPID 20 % is given for more than one week, your doctor will monitor the levels of fats in your blood.

If you receive more INTRALIPID 20 % than you should

Since a healthcare provider will administer INTRALIPID 20 %, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive INTRALIPID 20 %

Since a healthcare provider will administer INTRALIPID 20 %, it is unlikely that the dose will be missed.

If you stop using INTRALIPID 20 %

Not applicable

4. Possible side effects

INTRALIPID 20 % can have side effects.

Not all side effects reported for INTRALIPID 20 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving INTRALIPID 20 %, please consult your healthcare provider for advice.

Less frequently, some patients feel shivery and hot or cold. You may feel sick or actually be sick. If this happens to you, tell your doctor straight away.

Other side effects do occur. These include a severe allergic reaction, causing rash and problems with breathing. Stomach pain, headache, blood and circulatory problems, tiredness and prolonged, painful erections in men have also been reported, occurring immediately after receiving INTRALIPID 20 %.

INTRALIPID 20 % contains soybean oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reactions have been observed between soybean and peanuts (see "INTRALIPID 20 % should not be administered to you").

Some substances produced by the liver may increase in the blood and will be found on blood testing. One of these chemicals may cause jaundice – your skin and whites of eyes turn yellow. This form of jaundice is not infectious.

Prolonged treatment with INTRALIPID 20 % in infants has been reported to cause bleeding disorders.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of INTRALIPID 20 %.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicines regulatory authority in the country where the product is marketed.

5. How to store INTRALIPID 20 %

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not freeze.
- If INTRALIPID 20 % has been stored for a while, gently tip it upside down two or three times before using it.
- The package label has an expiry date. Do not use INTRALIPID 20 % after this date.
- Do not use if the container has been leaking.
- When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 2).
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What INTRALIPID 20 % contains:

Each 1 000 mL contains:

Purified soybean oil 200 g

The other ingredients are purified egg phospholipids, glycerol (anhydrous), sodium hydroxide (for pH-adjustment) and water for injections.

This medicine contains sugar (as glycerol anhydrous 22,0 g/1 000 mL).

What INTRALIPID 20 % looks like and contents of the pack

INTRALIPID 20 % is a white, homogenous emulsion.

INTRALIPID 20 % emulsion for intravenous infusion is packed in an infusion bag with an overpouch in the following pack sizes:

100 mL (10 x 100 mL or 20 x 100 mL)

250 mL

500 mL (12 x 500 mL)

1 000 mL

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration number

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Access to the corresponding Professional Information

The corresponding Professional Information (PI) can be accessed at https://www.fresenius-kabi.com/za/fresenius_kabi_south_africa_products

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

INTRALIPID® 20 % Emulsie vir intraveneuse infusie

Gesuiwerde sojaboonolie

Bevat suiker (as gliserol anhidries 22,0 g/1 000 mL)

Lees hierdie hele inligtingsblad aandagtig deur voordat INTRALIPID 20 % aan jou gegee word

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat in hierdie inligtingsblad is

1. Wat INTRALIPID 20 % is en waarvoor dit gebruik word
2. Wat jy moet weet voordat INTRALIPID 20 % aan jou gegee word
3. Hoe INTRALIPID 20 % aan jou toegedien sal word
4. Moontlike newe-effekte
5. Hoe om INTRALIPID 20 % te bewaar
6. Inhoud van die pak en ander inligting

1. Wat INTRALIPID 20 % is en waarvoor dit gebruik word

INTRALIPID 20 % voorsien energie en vette wat jou liggaam benodig, direk in die bloedstroom wanneer jy nie normaal kan eet nie. Dit word gebruik as deel van ‘n gebalanseerde intraveneuse dieet, saam met proteïene, koolhidrate, soute en vitamiene. INTRALIPID 20 % is veral nuttig na ernstige besering, brandwonde, of by pasiënte met ernstige infeksies.

2. Wat jy moet weet voordat INTRALIPID 20 % aan jou gegee word

INTRALIPID 20 % moenie aan jou toegedien word nie:

- indien jy hipersensitief (allergies) is vir eier-, soja- of grondboonproteïene of vir sojaboonolie of enige van die ander bestanddele van INTRALIPID 20 % (gelys in afdeling 6).
- indien jou liggaam tans in skok is (as gevolg van hewige bloedverlies of allergiese reaksie), of indien jy probleme het met vetmetabolisme.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat jy ingespuit word:

Neem spesiale sorg met INTRALIPID 20 %:

- indien jy probleme met jou lewer, niere of pankreas het
- indien jy hoë cholesterol het
- indien jy hoë bloedsuiker (diabetes mellitus) het
- indien jy tans ‘n infeksie het
- indien jy skildklierprobleme het.

Jou dokter sal moontlik gereelde bloedtoetse wil laat doen om seker te maak dat jou liggaam INTRALIPID 20 % korrek gebruik.

Geen ander medisyne moet by INTRALIPID 20 % gevoeg word nie, tensy dit veilig is om dit te doen.

Kinders

Lig jou dokter in indien jou baba geelsug (vergeling van die vel en/of oë) of longprobleme soos pulmonêre hipertensie het. Jou dokter sal moontlik gereelde bloedtoetse wil doen.

Jou gesondheidsorgverskaffer sal seker maak dat INTRALIPID 20 % teen ligblootstelling

beskerm word tydens toediening aan babas jonger as 2 jaar.

Ander medisyne en INTRALIPID 20 %

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Vertel jou dokter indien jy enige van die volgende gebruik of neem:

- Insulien vir die behandeling van hoë bloedsuiker (diabetes mellitus)
- Heparien vir die behandeling en voorkoming van bloedklonte in die are, slagare of longe
- Warfarien, wat voorkom dat bloedklonte vorm of groter groei in jou bloed en bloedvate.

INTRALIPID 20 % saam met kos, vloeistowwe en alkohol

Nie van toepassing nie

Swangerskap en borsvoeding

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om ‘n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy INTRALIPID 20 % ontvang.

Bestuur en die gebruik van masjinerie

Geen effek op die vermoë om te bestuur of masjinerie te gebruik, word verwag nie.

Dit is nie altyd moontlik om te voorspel tot watter mate INTRALIPID 20 % die daaglikse aktiwiteite van ‘n pasiënt kan beïnvloed nie. Pasiënte moet seker maak dat hulle nie aan die bogenoemde aktiwiteite deelneem, totdat hulle nie bewus is tot watter mate INTRALIPID 20 % hulle affekteer nie.

INTRALIPID 20 % bevat:

INTRALIPID 20 % bevat sojaboonolie en eierfosfolipiede, wat in skaarse gevalle allergiese reaksies kan veroorsaak. Kruis allergiese reaksies is waargeneem tussen sojabone en grondboontjies (sien “INTRALIPID 20 % moenie aan jou toegedien word nie”).

3. Hoe INTRALIPID 20 % aan jou toegedien sal word

Daar sal nie van jou verwag word om INTRALIPID 20 % aan jouself te gee nie. Dit sal aan jou gegee word deur 'n persoon wat opgelei is om dit te doen.

INTRALIPID 20 % word gewoonlik deur ‘n aar saam met ander oplossings, soos aminosure (proteïene), suikers, soute en vitamiene, gegee.

Dosis

Jou dokter sal die geskikte volume INTRALIPID 20 % wat aan jou toegedien moet word, voorskryf.

Indien jy die indruk het dat die effek van INTRALIPID 20 % te sterk of te swak is, lig jou dokter of apteker in.

Metode van toediening

INTRALIPID 20 % word stadig deur middel van ‘n drup deur ‘n klein plastiese buisie (‘n kateter), direk in jou bloedstroom gegee. ‘n Elektroniese pomp kan gebruik word om die spoed van jou drup te beheer.

Hoe gereeld jou medisyne gegee sal word

INTRALIPID 20 % sal gewoonlik elke dag gegee word, totdat jy weer kan begin eet.

Tydsduur van behandeling

Jou dokter sal jou inlig hoe lank jou behandeling met INTRALIPID 20 % sal duur.

Indien INTRALIPID 20 % vir meer as een week gegee word, sal jou dokter die vetvlakke in jou bloed moniteer.

As jy meer INTRALIPID 20 % ontvang as wat jy moet

Aangesien ‘n gesondheidsorgverskaffer INTRALIPID 20 % sal toedien, sal hy/sy die dosis beheer. Nietemin, in die geval van oordosering, sal jou dokter die oordosering hanteer.

Indien jy vergeet om INTRALIPID 20 % te gebruik

Aangesien ‘n gesondheidsorgverskaffer INTRALIPID 20 % sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

Indien jy die gebruik van INTRALIPID 20 % staak

Nie van toepassing nie

4. Moontlike newe-effekte

INTRALIPID 20 % kan newe-effekte hê.

Nie alle newe-effekte wat vir INTRALIPID 20 % aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy INTRALIPID 20 % ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Minder gereeld kan sommige pasiënte bewerig voel en warm of koud kry. Jy kan siek voel of inderdaad siek wees. Indien dit met jou gebeur, lig jou dokter dadelik in.

Ander newe-effekte kom wel voor. Dit sluit ‘n ernstige allergiese reaksie, wat uitslag en asemhalingsprobleme veroorsaak, in. Maagpyn, hoofpyn, bloed- en sirkulasieprobleme, moegheid, en verlengde, pynlike ereksies by mans, wat dadelik ná ontvangs van INTRALIPID 20 % voorkom, is ook aangemeld.

INTRALIPID 20 % bevat sojaboonolie en eierfosfolipiede, wat in skaarse gevalle allergiese reaksies kan veroorsaak. Kruis allergiese reaksies is waargeneem tussen sojabone en grondboontjies (sien “INTRALIPID 20 % moenie aan jou toegedien word nie”).

Sommige stowwe wat deur die lewer vervaardig word, kan in die bloed toeneem, en dit sal met bloedtoetse opgemerk word. Een van hierdie chemiese stowwe kan geelsug veroorsaak – jou vel en wit van die oë, verkleur geel. Hierdie vorm van geelsug is nie aansteeklik nie.

Daar is aangemeld dat verlengde behandeling met INTRALIPID 20 % by babas, bloedingsversteurings kan veroorsaak.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, raadpleeg jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van INTRALIPID 20 % te verskaf.
Pasiënte word versoek om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan hulle gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die produk bemark word.

5. Hoe om INTRALIPID 20 % te bewaar

- Bewaar alle medisyne buite bereik van kinders.
- Bewaar by of onder 25 °C.
- Moenie vries nie.
- Indien INTRALIPID 20 % vir ‘n rukkie gestoor was, kantel dit twee of drie keer versigtig onderstebo voordat dit gebruik word.
- Die verpakkingsetiket het ‘n vervaldatum. Moenie INTRALIPID 20 % ná hierdie datum gebruik nie.
- Moenie gebruik indien die houer gelek het nie.
- Wanneer dit by pasgeborenes en kinders jonger as 2 jaar gebruik word, moet die oplossing (in sakkies en in toedieningstelle) teen ligblootstelling beskerm word totdat

die toediening voltooi is (sien afdeling 2).

- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat INTRALIPID 20 % bevat:

Elke 1 000 mL bevat:

Gesuiwerde sojaboonolie 200 g

Die ander bestanddele is gesuiwerde eierfosfolipiede, gliserol (anhidries), natriumhidroksied (vir pH-aanpassing) en water vir inspuitings.

Hierdie medisyne bevat suiker (as gliserol anhidries 22,0 g/1000 mL).

Hoe INTRALIPID 20 % lyk en inhoud van die pak

INTRALIPID 20 % is ‘n wit, homogene emulsie.

INTRALIPID 20 % emulsie vir intraveneuse infusie word verpak in ‘n infusiesak met ‘n oorsak in die volgende verpakkingsgroottes:

100 mL (10 x 100 mL or 20 x 100 mL)

250 mL

500 mL (12 x 500 mL)

1 000 mL

Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van Sertifikaat van Registrasie

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Hierdie inligtingsblad is laas hersien op

20 Mei 2026

Registrasienommer

K/25.2/316

Toegang tot die ooreenstemmende Professionele Inligting

Die ooreenstemmende Professionele Inligting (PI) is beskikbaar by https://www.fresenius-kabi.com/za/fresenius_kabi_south_africa_products