PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FORLAX®

Powder for solution

Read all of this leaflet carefully because it contains important information for you.
FORLAX® is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use FORLAX® carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share FORLAX® with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days

1. WHAT FORLAX® CONTAINS
Each sachet contains 10 g of macrogol 4000.

The other ingredients are orange grapefruit flavour (orange and grapefruit oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanol, beta gamma hexanol, maltodextrin, gum arabic, , preservatives: BHA; sulphur dioxide); saccharin sodium.

Contains sugar: sorbitol.

2. WHAT FORLAX® IS USED FOR
FORLAX® is an osmotic laxative used for the treatment of chronic functional constipation in adults and in children from 8 years old.

If symptoms persist despite associated dietary measures, you should contact a doctor.

3. BEFORE YOU TAKE FORLAX®
Do not take FORLAX®:
- If you are hypersensitive (allergic) to macrogol (polyethylene glycol) or any of the ingredients of FORLAX®. (Refer to "WHAT FORLAX® CONTAINS", above.)
- If you suffer from severe inflammatory bowel disease (such as ulcerative colitis or Crohn's disease) or an abnormally distended colon (megacolon) associated with symptomatic narrowing of the bowel (stenosis).
- If you have a hole in the wall of the bowel (intestinal perforation) or are at risk of an intestinal perforation.
- If you have impaired bowel passage caused by paralysis of the bowel or a bowel obstruction (ileus) or a suspected bowel (intestinal) obstruction.
- If you are suffering from abdominal pain without knowing the cause.
- If you have a hereditary fructose intolerance.

Take special care with FORLAX®:
An organic disorder should have been ruled out before starting treatment.
FORLAX® should remain a temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3-month treatment course in children. In adults the need for continued treatment should be reassessed at 3 months.

The treatment of constipation with any medicinal product is only an adjuvant to a healthy lifestyle and diet, for example:
- increased intake of liquids and dietary fibre,
- appropriate physical activity and rehabilitation of the bowel reflex.

Cases of allergic reactions involving reddening of the skin, itchy nettle rash and swelling (oedema) have been reported after intake of products containing macrogol (polyethylene glycol). Cases of severe allergic shock reactions (affecting the heart, circulation and/or breathing) have been reported.

In case of diarrhoea, patients with impaired liver or kidney function, patients taking diuretics and elderly patients should contact a doctor, who may consider whether electrolyte control is required.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:
No studies on the effects on the ability to drive and use machines have been performed.

Important information about some of the ingredients of FORLAX®:
Patients with hereditary fructose intolerance should not take FORLAX®.

FORLAX® does not contain a significant quantity of sugar or sugar alcohols and is suitable for use by diabetics and patients needing a galactose-free diet.

Taking other medicines with FORLAX®:
Always tell your health care professional if you are taking any other medicines.
(This includes complementary or traditional medicines.)

4. HOW TO TAKE FORLAX®
Do not share medicines prescribed for you with any other person.

Always take FORLAX® exactly as described in this leaflet. You should check with your doctor, pharmacist or other healthcare professional if you are not sure.

Dissolve the contents of each sachet in a glass of water immediately before use and drink the liquid.
Unless otherwise prescribed by your doctor, the usual dose is:
- 1-2 sachets per day, preferably taken as a single dose in the morning.

For single use only. Discard unused solution.

The daily dose can be adapted according to the effect obtained and may range from one sachet every other day (especially in children) to 2 sachets per day.

The effect of FORLAX® becomes apparent 24 to 48 hours after intake.

In children, the duration of treatment with FORLAX® should not exceed 3 months.

Treatment-induced restoration of bowel movements should be maintained by a healthy lifestyle and diet (see the relevant information under **'Take special care with FORLAX®'**.)

If you have the impression that the effect of FORLAX® is too strong or too weak, talk to your doctor, pharmacist or other healthcare professional.

If you take more FORLAX® than you should:
This may cause diarrhoea, which disappears when treatment is temporarily interrupted or the dosage reduced.

Excessive fluid loss caused by diarrhoea or vomiting may require correction of electrolyte disturbances and, if this occurs, you should contact a doctor.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take FORLAX®:
Do not take a double dose to make up for forgotten doses.

5. POSSIBLE SIDE EFFECTS
FORLAX® can cause side effects. The following side effects may occur:

If any of the following happen, stop taking FORLAX® and tell your doctor immediately or go to the casualty department at your nearest hospital:
Hypersensitivity (allergic) reactions -
- Itching of the skin with compulsive scratching, rash, itching, hives, reddening of the skin, sudden life-threatening allergic reaction (anaphylactic shock).
- Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat (angioedema) which may cause difficulty in swallowing or breathing.
- Diarrhoea leading to electrolyte disorders (hyponatraemia, hypokalaemia) and/or dehydration, especially in elderly patients.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FORLAX®. You may need urgent medical attention or hospitalisation.

Other side effects that may occur include:
Adults
The side effects mainly concern the gastrointestinal tract.
- Frequent: stomach swelling (abdominal distension) and/or pain, nausea, diarrhoea.
- Less frequent: vomiting, and the usual consequences of diarrhoea – urgency to defaecate and faecal incontinence.

Excessive doses may cause diarrhoea which may disappear when the dosage is reduced or treatment temporarily interrupted.

Children
The side effects concern the gastrointestinal tract.
- Frequent: diarrhoea and abdominal pain.
- Large doses may cause diarrhoea which may disappear when the dosage is reduced or treatment temporarily interrupted. Diarrhoea may cause soreness around the anus.
- Less frequent: stomach swelling (abdominal distension), vomiting and nausea.

Not all side effects reported for FORLAX® are included in this leaflet.
Should your general health worsen while taking FORLAX®, please consult your doctor, pharmacist or other healthcare professional for advice.

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

6. STORING AND DISPOSING OF FORLAX®
Store all medicines out of reach of children.
Store at or below 30ºC. For single use only. Discard unused solution.
Do not use after the expiry date stated on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF FORLAX®
Single dose white sachets packed in cardboard cartons of 10 or 20. The sachet consists of paper/aluminium/polyethylene layers.

8. IDENTIFICATION OF FORLAX®
A white or almost white powder, having a reminiscent odour of orange and grapefruit.

9. REGISTRATION NUMBER
45/11.5/1129

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Litha Pharma (Pty) Ltd
106, 16th Road
Midrand
1686

1050522 RV

11. DATE OF PUBLICATION
23 March 2015

LP2139 06/2017

VOUBILJET

SKEDULERINGSTATUS: S0

EIENDOMSNAAM (en DOSEERVORM):

FORLAX®

Poeier vir oplossing

SAMESTELLING:
Elke sakkie bevat 10 g makrogol 4000.

Mengmiddels: lemoen-pomelo-geur (lemoen- en pomelo-olies, gekonsentreerde lemoensap, sitraal, asetaldehied, linaloël, etielbutiraat, alfa-terpineol, oktanol, beta-gamma-heksanol, maltodekstrien, arabiese gom, preserveermiddels: BHA, swaeldioksied); natriumsakkarien.

Bevat suiker: sorbitol.

FARMAKOLOGIESE KLASSIFIKASIE:
A 11.5 Lakseermiddels

FARMAKOLOGIESE WERKING:
'n Makrogol met 'n hoë molekulêre gewig (4000) is lang liniêre polimere wat retensie van watermolekules, deur middel van waterstofbinding, veroorsaak. Wanneer dit deur die orale roete toegedien word, lei dit tot 'n toename in die volume van intestinale vloeistowwe.

Die volume van intestinale vloeistof wat nie geabsorbeer word nie is vir die lakserende eienskappe van die oplossing verantwoordelik.

Farmakokinetika:
Die farmakokinetiese data bevestig dat makrogol 4000 nie gastrointestinale resorpsie, of biotransformasie na orale inname ondergaan nie.

INDIKASIES:
Simptomatiese behandeling van chroniese funksionele hardlywigheid in volwassenes en kinders van 8 jaar en ouer.

'n Organiese versteuring moet eers uitgeskakel word voor inisiasie van behandeling. FORLAX® behoort 'n tydelike bykomende behandeling vorm tot 'n meer toepaslike lewenstyl te wees. En korrekte eetgewoontes vir die behandeling van hardlywigheid met 'n maksimum behandelingskursus van 3 maande by kinders. Indien simptome aanhou ten spyte van ge-assosieerde korrekte diëeetmaatreëls, behoort 'n onderliggende oorsaak vermoed en behandel te word.

KONTRA-INDIKASIES:
- Ernstige inflammatoriese dermsiekte (soos ulseratiewe kolitis, Crohn se siekte) of toksiese megakolon, geassosieer met simptomatiese stenose.
- Spysverteringsperforasie, of risiko van spysverteringsperforasie.
- Ileus of vermoede van intestinale obstruksie.
- Pynlike abdominale sindrome van onbepaalbare oorsaak.
- Hipersensitiwiteit teen makrogol (poliëtileenglikol) of enige van die mengmiddels.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Die behandeling van hardlywigheid met enige medisinale produk is slegs bykomend tot 'n gesonde lewenstyl en diëet, byvoorbeeld:
- verhoogde inname van vloeistowwe en diëetvesel,
- toepaslike fisiese aktiwiteit en rehabilitasie van die dermrefleks.

In gevalle van diarree, moet omsigtigheid beoefen word by pasiënte wat neig tot versteurings van die water-elektrolietbalans (bv. Pasiënte met ingekorte hepatiese of renale funksie of pasiënte wat diuretika neem) en elektrolietbeheer moet in gedagte gehou word.

Spesiale voorsorgmaatreëls:
Gevalle van hipersensitiwiteitsreaksies (veluitslag, urtikarie, edeem) is aangemeld met medisyne wat makrogol (poliëtileenglikol) bevat. Gevalle van anafilaktiese skok is al aangemeld.

FORLAX® bevat nie 'n betekenisvolle hoeveelheid suiker of poliol nie, en dit kan vir diabetiese pasiënte of pasiënte op 'n galaktose-vrye diëet, voorgeskryf word.

Pasiënte met oorgeërfde probleme van fruktose-intoleransie behoort nie hierdie medisinale produk te gebruik nie.

Effekte op die vermoë om te bestuur en masjiene te gebruik:
Geen navorsing oor die effekte op die vermoë om te bestuur en masjiene te gebruik, is uitgevoer nie.

INTERAKSIES:
Geen bekend nie.

SWANGERSKAP EN LAKTASIE:
Swangerskap:
Veilige gebruik tydens swangerskap is nie vasgestel nie. Daar is geen toereikende data van die gebruik van FORLAX® by swanger vrouens beskikbaar nie.

Laktasie:
Daar is geen data oor die uitskeiding van makrogol 4000 in borsmelk nie. Omdat makrogol 4000 nie beduidend geabsorbeer word nie, mag FORLAX® gedurende laktasie toegedien word.

forlax®
Makrogol 4000

DOSIS EN GEBRUIKSAANWYSINGS:
Orale gebruik:
1 tot 2 sakkies per dag, wat verkieslik as 'n enkeldosis in die oggend geneem word. Elke sakkie behoort in 'n glas water net voor gebruik, opgelos te word. Slegs vir enkelgebruik bedoel. Raak van ongebruikte oplossing ontslae.

Die uitwerking van FORLAX® word binne 24 tot 48 uur na toediening merkbaar.

By kinders behoort behandeling nie 3 maande te oorskry nie as gevolg van 'n gebrek aan data vir tydperke van langer as 3 maande. Behandeling-geïnduseerde herstel van dermbewegings sal deur lewenstyl en diëetmaatreëls volhou word.

By volwassenes behoort die noodsaaklikheid om behandeling voort te sit, op 3 maande weer geëvalueer word.

Die daaglikse dosis behoort volgens die kliniese uitwerking aangepas te word en dit mag wissel van een sakkie elke tweede dag (veral by kinders) tot 2 sakkies per dag.

NEWE-EFFEKTE:

Volwassenes
Ongewenste effekte wat aangemeld is tydens kliniese studies wat ongeveer 600 pasiënte betrek het, met die volgende frekwensies het hoofsaaklik die gastrointestinale stelsel geraak:

Algemeen (≥1/100, <1/10): abdominale distensie en/of pyn, naarheid, diarree.

Ongewoon (≥1/1000, <1/100): braking, en die meer algemene gevolge van diarree - ontlastingsdrang en fekale inkontinensie.

Addisionele inligting van na-bemarkings-waarneming sluit gevalle van hipersensitiwiteitsreaksies in - pruritus, urtikarie, veluitslag, edeem van die gesig, angio-edeem en geïsoleerde gevalle van anafilaktiese skok is aangemeld.

Oormatige dosisse mag diarree veroorsaak, wat mag verdwyn wanneer die dosis verlaag word of behandeling tydelik onderbreek word.

Kinders
Ongewenste effekte is aangemeld tydens kliniese studies wat ongeveer 147 kinders van 6 maande tot 15 jaar betrek het, met die volgende frekwensies. Die uitwerking het hoofsaaklik die gastroïntestinale sisteem geraak:

Gastroïntestinale versteurings:

Algemeen (≥1/100, <1/10): diarree en abdominale pyn.

Ongewoon (≥1/1000, <1/100): uitsetting, braking en naarheid.

Daar is geen addisionele inligting van na-bemarkings-waarneming nie - hipersensitiwiteitsreaksies mag voorkom soos by volwassenes aangemeld.

Groot dosisse mag diarree veroorsaak, wat mag verdwyn wanneer die dosis verlaag word of tydelik onderbreek word. Diarree kan perianale pyn veroorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Oordosis lei tot diarree wat verdwyn wanneer behandeling tydelik onderbreek word, of die dosis verlaag word.

Oormatige vloeistofverlies weens diarree of braking mag regstelling van elektrolietversteurings noodsaak.

Gevalle van aspirasie is aangemeld wanneer oormatige volumes van poliëtileenglikol en elektroliete met 'n nasogastriese buis toegedien is.
Neurologies ingekorte kinders wat oromotordisfunksie het, is veral aan risiko van aspirasie blootgestel.

IDENTIFIKASIE:
'n Wit of naaswit poeier met 'n reuk wat herinner aan lemoen en pomelo.

AANBIEDING:
Enkeldosis wit sakkies verpak in kartondose van 10 en 20. Die sakkie bestaan uit papier/ aluminium/ poliëtileen-lae.

BERGINGSAANWYSINGS:
Bewaar by of onder 30ºC. Hou buite bereik van kinders.
Slegs vir enkelgebruik bedoel.
Raak van ongebruikte oplossing ontslae.

REGISTRASIENOMMER:
45/11.5/1129

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Litha Pharma (Edms) Bpk
16de Weg 106
Midrand
1686

DATUM VAN PUBLIKASIE VAN VOUBILJET:
23 Maart 2015

PACKAGE INSERT

SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM):

FORLAX®

Powder for solution

COMPOSITION:
Each sachet contains 10 g of macrogol 4000.

Excipients: orange grapefruit flavour (orange and grapefruit oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanol, beta gamma hexanol, maltodextrin, gum arabic, preservatives: BHA; sulphur dioxide); saccharin sodium.
Contains sugar: sorbitol.

PHARMACOLOGICAL CLASSIFICATION:
A 11.5 Laxatives

PHARMACOLOGICAL ACTION:
High molecular weight (4000) macrogols are long linear polymers which retain water molecules by means of hydrogen bonds. When administered by the oral route, they lead to an increase in volume of intestinal fluids.

The volume of unabsorbed intestinal fluid accounts for the laxative properties of the solution.

Pharmacokinetics:
The pharmacokinetic data confirm that macrogol 4000 undergoes neither gastrointestinal resorption nor biotransformation following oral ingestion.

INDICATIONS:
Symptomatic treatment of chronic functional constipation in adults and children aged 8 years and above.
An organic disorder should have been ruled out before initiation of treatment. FORLAX® should remain a temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3-month treatment course in children. If symptoms persist despite associated dietary measures, an underlying cause should be suspected and treated.

CONTRA-INDICATIONS:
- Severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or toxic megacolon, associated with symptomatic stenosis.
- Digestive perforation or risk of digestive perforation.
- Ileus or suspicion of intestinal obstruction.
- Painful abdominal syndromes of indeterminate cause.
- Hypersensitivity to macrogol (polyethylene glycol) or to any of the excipients.

WARNINGS AND SPECIAL PRECAUTIONS:
The treatment of constipation with any medicinal product is only an adjuvant to a healthy lifestyle and diet, for example:
- increase intake of liquids and dietary fibre,
- appropriate physical activity and rehabilitation of the bowel reflex.

In case of diarrhoea, caution should be exercised in patients prone to disturbances of water-electrolyte balance (e.g. Patients with impaired hepatic or renal function or patients taking diuretics) and electrolyte control must be considered.

Special precautions:
Cases of hypersensitivity reactions (rash, urticaria, oedema) have been reported with medicines containing macrogol (polyethylene glycol). Cases of anaphylactic shock have been reported.

FORLAX® does not contain a significant quantity of sugar or polyol and can be prescribed to diabetic patients or patients on a galactose-free diet.

Patients with hereditary problems of fructose intolerance should not take this medicinal product.

Effects on ability to drive and use machines:
No studies on the effects on the ability to drive and use machines have been performed.

INTERACTIONS:
None known.

PREGNANCY AND LACTATION:
Pregnancy:
Safe use during pregnancy has not been established. There is no adequate data on the use of FORLAX® in pregnant women.

Lactation:
There is no data on the excretion of macrogol 4000 in breast milk. As macrogol 4000 is not significantly absorbed, FORLAX® may be administered during lactation.

DOSAGE AND DIRECTIONS FOR USE:
Oral use.
1 to 2 sachets per day, preferably taken as a single dose in the morning. Each sachet should be dissolved in a glass of water just before use. For single use only. Discard unused solution.

The effects of FORLAX® becomes apparent within 24 to 48 hours after its administration.

In children, treatment should not exceed 3 months, due to the lack of clinical data for more than 3 months. Treatment-induced restoration of bowel movements will be maintained by lifestyle and dietary measures.

In adults the need for continuing treatment should be reassessed at 3 months.
The daily dose should be adapted according to the clinical effects and may range from one sachet every other day (especially in children) up to 2 sachets a day.

SIDE EFFECTS:
Adults:
Undesirable effects reported during clinical trials involving almost 600 patients with the following frequencies have mainly concerned the gastrointestinal system:

Common (≥ 1/100, < 1/10): abdominal distension and/or pain, nausea, diarrhoea.

Uncommon (≥ 1/1000, < 1/100): vomiting, and the more common consequence of the diarrhoea – urgency to defaecate and faecal incontinence.

Additional information from post-marketing surveillance included cases of hypersensitivity reactions – pruritis, urticaria, rash, face oedema, angioedema and isolated cases of anaphylactic shock have been reported.

Excessive doses may cause diarrhoea, which may disappear when the dosage is reduced or treatment temporarily interrupted.

Children:
Undesirable effects have been reported during clinical trials involving 147 children aged from 6 months to 15 years with the following frequencies. The effects concerned the gastrointestinal system:

Gastrointestinal disorders:

Common (≥ 1/100, < 1/10): diarrhoea and abdominal pain.

Uncommon (≥ 1/1000, < 1/100): bloating, vomiting and nausea.

There is no additional information from post-marketing surveillance – hypersensitivity reactions may occur as reported in adults.

Large doses may cause diarrhoea, which may disappear when the dosage is reduced or temporarily interrupted. Diarrhoea may cause perianal soreness.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Overdose leads to diarrhoea which disappears when treatment is temporarily interrupted or the dosage is reduced.

Excessive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

Cases of aspiration have been reported when extensive volumes of polyethylene glycol and electrolytes were administered with a nasogastric tube. Neurologically impaired children who have oromotor dysfunction are particularly at risk of aspiration.

IDENTIFICATION:
A white or almost white powder having a reminiscent odour of orange and grapefruit.

PRESENTATION:
Single dose white sachets packed in cardboard cartons of 10 or 20. The sachet consists of paper/aluminium/polyethylene layers.

STORAGE INSTRUCTIONS:
Store at or below 30ºC. Keep out of the reach of children.
For single use only. Discard unused solution.

REGISTRATION NUMBER:
45/11.5/1129

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Litha Pharma (Pty) Ltd
106, 16th Road
Midrand
1686

DATE OF PUBLICATION OF PACKAGE INSERT
23 March 2015

PASIËNTINLIGTINGSBROSJURE

SKEDULERINGSTATUS S0

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM

FORLAX®

Poeier vir oplossing

Lees hierdie hele brosjure versigtig deur omdat dit belangrike inligting vir jou bevat.
FORLAX® is sonder 'n dokter se voorskrif beskikbaar, sodat u 'n matige siekte kan behandel.
Desnieteenstaande behoort u FORLAX® steeds versigtig te gebruik om die beste resultate daarmee te bereik.

- Hou hierdie brosjure. U mag dit weer moet lees.
- Moenie FORLAX® met enige ander persone deel nie.
- Indien u verdere inligting of advies nodig het, vra u apteker.
- U moet 'n dokter raadpleeg indien u simptome vererger en nie na 3 dae verbeter nie.

1. WAT FORLAX® BEVAT
Elke sakkie bevat 10 g van makrogol 4000.
Die ander bestanddele is lemoen-pomelo-geur (lemoen-en-pomelo-olies, gekonsentreerde lemoensap, sitraal, asetaldehied, linaloöl, etielbutiraat, alfa-terpineol, oktanol, beta-gamma-heksanol, maltodekstrien, arabiese gom, preserveermiddels: BHA, swaeldioksied); natriumsakkarien.

Bevat suiker: sorbitol.

2. WAARVOOR FORLAX® GEBRUIK WORD
FORLAX® is 'n osmotiese lakseermiddel wat gebruik word vir die behandeling van chroniese funksionele hardlywigheid in volwassenes en in kinders vanaf die ouderdom van 8 jaar.

Indien simptome aanhou ten spyte van geassosieerde dieëtmaatreëls, behoort jy 'n dokter te raadpleeg.

3. VOORDAT U FORLAX® NEEM
Moet nie FORLAX® neem nie:
- Indien u hipersensitief (allergies) vir makrogol (poliëtileenglikol) of enige van die ander bestanddele in FORLAX® is. (Verwys na "WAT FORLAX® BEVAT").
- Indien u aan 'n ernstige inflammatoriese dermsiekte ly (soos ulseratiewe kolitis of Crohn se siekte) of 'n abnormaal uitgesitte kolon (megakolon) het, wat met simptomatiese vernouing van die derm (stenose) gepaardgaan.
- Indien u 'n opening in die wand van die derm (intestinale perforasie) het of aan die risiko van 'n intestinale perforasie blootgestel is.
- Indien u belemmerde derm passering het wat deur paralise van die derm veroorsaak word, of 'n dermobstruksie (ileus) of 'n derm intestinale obstruksie vermoed word.
- Indien u aan abdominale pyn ly sonder om te weet wat die oorsaak daarvan is.
- Indien u oorgeërfde fruktose-intoleransie het.

Neem spesiale sorg met FORLAX®
'n Organiese versteuring moet eers uitgeskakel word voor behandeling begin kan word.
FORLAX® behoort 'n tydelike bykomende behandeling te bly tot 'n toepaslike lewenstyl en die dieëtkundige hantering van hardlywigheid, met 'n maksimum behandelingskursus van 3 maande by kinders. By volwassenes behoort die noodsaaklikheid van voortgesette behandeling op 3 maande weer geëvalueer te word.

Die behandeling van hardlywigheid met enige medisinale produk is slegs bykomend tot 'n gesonde lewenstyl en dieët, byvoorbeeld:

- verhoogde inname van vloeistowwe en dieëtvesel,
- toepaslike fisiese aktiwiteit en rehabilitasie van die dermrefleks.

Gevalle van allergiese reaksies soos rooiheid van die vel, jeukerige netelroos en swelling (edeem) is aangemeld na inname van produkte wat makrogol (poliëtileenglikol) bevat. Gevalle van ernstige allergiese skokreaksies (wat die hart, sirkulasie en/of asemhaling geaffekteer het), is al aangemeld.

In die geval van diarree, behoort pasiënte met ingekorte lewer- of nierfunksie, pasiënte wat diuretika neem, en bejaarde pasiënte 'n dokter te kontak, wat sal oorweeg of elektrolietbeheer nodig is.

Swangerskap en borsvoeding:
Indien u swanger is, of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg voordat u hierdie medisyne neem.

Bestuur en die gebruik van masjiene:
Daar is geen navorsing oor die effekte op die vermoë om te bestuur en masjiene te gebruik, uitgevoer nie.

Belangrike inligting oor sommige van die bestanddele in FORLAX®:
Pasiënte met oorgeërfde fruktose-intoleransie behoort FORLAX® nie te neem nie.

FORLAX® bevat nie 'n betekenisvolle hoeveelheid suiker of poliol nie, en dit kan vir diabetiese pasiënte of pasiënte op 'n galaktose-vrye dieët, voorgeskryf word.

Neem van ander medisyne saam met FORLAX®:
U moet altyd u gesondheidsorgdeskundige vertel indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).

4. HOE OM FORLAX® TE NEEM
Moenie medisyne wat vir u voorgeskryf is, met 'n ander persoon deel nie.

Neem FORLAX® altyd presies soos dit in hierdie brosjure beskryf is. Jy behoort met jou dokter, apteker of ander gesondheidsorgdeskundige te gesels as u nie seker is nie.

Los die inhoud van elke sakkie in 'n glas water op en drink die vloeistof onmiddellik.

Tensy anders deur u dokter voorgeskryf, is die gebruiklike dosis:

1-2 sakkies per dag, wat verkieslik as 'n enkeldosis in die oggend geneem word.

Slegs vir eenmalige gebruik. Raak van ongebruikte oplossing ontslae.

Die daaglikse dosis kan volgens die uitwerking wat bereik word aangepas word en mag wissel van een sakkie elke tweede dag (veral by kinders) tot 2 sakkies per dag.

Die uitwerking van FORLAX® word binne 24 tot 48 uur na toediening merkbaar.

By kinders behoort die duur van behandeling met FORLAX® 3 maande nie te oorskry nie.
Behandeling-geïnduseerde herstel van dermbewegings sal deur lewenstyl en dieëtmaatreëls onderhou word (sien relevante inligting onder **'Neem spesiale sorg met FORLAX®'**).

Indien u onder die indruk verkeer dat die effek van FORLAX® te sterk of te swak is, moet u met u dokter, apteker of ander gesondheidsorgdeskundige raadpleeg.

Indien jy meer FORLAX® neem, as wat jy behoort te neem:
Dit mag diarree veroorsaak, wat verdwyn wanneer behandeling tydelik onderbreek word of as die dosis verlaag word.

Oormatige vloeistofverlies wat deur diarree of braking veroorsaak is mag korreksie van elektrolietversteurings benodig, en as dit voorkom, behoort u 'n dokter te raadpleeg.

In 'n geval van oordosering moet u met u dokter of apteker raadpleeg. Indien beide nie beskikbaar is, moet u hulp by die naaste hospitaal of gifbeheersentrum kry.

Indien u vergeet om 'n dosis FORLAX® te neem:
Moenie 'n dubbele dosis neem om op te maak vir vergete dosisse nie.

5. MOONTLIKE NEWE-EFFEKTE
FORLAX® kan newe-effekte veroorsaak. Die volgende newe-effekte mag voorkom.

Indien enige van die volgende gebeur, moet u inname van FORLAX® staak en u dokter dadelik daarvan vertel of na die noodafdeling van u naaste hospitaal gaan:
Hipersensitiwiteitsreaksies (allergiese reaksies) -

- Jeuk van die vel met kompulsiewe krap, veluitslag, jeuk, galbulte, vel wat rooi word, skielike lewensbedreigende allergiese reaksies (anafilaktiese skok).
- Swelling van die hande, voete, enkels, gesig, lippe, mond, tong, of keel (angio-edeem), wat probleme met sluk, of asemhaling mag veroorsaak.
- Diarree wat tot elektrolietversteurings aanleiding gee (hiponatremie, hipokalemie) en/of dehidrasie, veral by bejaarde pasiënte.

Dit is almal baie ernstige newe-effekte. Indien u dit ontwikkel, het u moontlik 'n ernstige allergiese reaksie teen FORLAX® gehad. U het moontlik dringende mediese aandag of hospitalisasie nodig.

Ander newe-effekte wat mag voorkom, sluit in:

Volwassenes
Die newe-effekte het hoofsaaklik die spysverteringskanaal betrek.

- Frekwent: swelling van die maag (abdominale distensie) en/of pyn, naarheid, diarree.
- Minder frekwent: braking, en die algemene gevolge van diarree - ontlastingsdrang en fekale inkontinensie.

Oormatige dosisse mag diarree veroorsaak, wat mag verdwyn wanneer die dosis verlaag word of behandeling tydelik onderbreek word.

Kinders

Die newe-effekte het hoofsaaklik die gastroïntestinale sisteem betrek:

- Frekwent: diarree en abdominale pyn.
- Groot dosisse mag diarree veroorsaak, wat mag verdwyn wanneer die dosis verlaag word of tydelik onderbreek word. Diarree kan pyn rondom die anus veroorsaak.
- Minder frekwent: swelling van die maag (abdominale distensie), braking en naarheid.

Nie alle newe-effekte wat vir FORLAX® aangemeld is, word in hierdie brosjure ingesluit nie. Indien u algemene gesondheid sou vererger terwyl jy FORLAX® neem, moet u asseblief u dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg.

Indien u bewus word van enige newe-effekte wat nie in hierdie brosjure ingesluit word nie, moet u asseblief u dokter of apteker raadpleeg.

6. BERGING EN WEGDOENING VAN FORLAX®
Bêre alle medisyne buite die bereik van kinders.
Bewaar by of onder 30ºC. Slegs vir enkelgebruik bedoel. Raak van ongebruikte oplossing ontslae.
Moenie na die vervaldatum wat op die kartonhouer genoem word, gebruik nie.
Gee alle ongebruikte medisyne aan u apteker terug.
Moenie ongebruikte medisyne in dreine of rioolsisteeme (bv. toilette) weggooi nie.

7. AANBIEDING VAN FORLAX®
Enkeldosis wit sakkies verpak in kartondose van 10 en 20. Die sakkie bestaan uit papier/ aluminium/ poliëtileen-lae.

8. IDENTIFIKASIE VAN FORLAX®
'n Wit of naaswit poeier met 'n reuk wat herinner aan lemoen en pomelo.

9. REGISTRASIENOMMER
45/11.5/1129

10. NAAM EN BESIGHEIDSADRES VAN DIE REGISTRASIEHOUER
Litha Pharma (Edms) Bpk
16de Weg 106
Midrand
1686

11. DATUM VAN PUBLIKASIE
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