

SCHEDULING STATUS S0

PROPRIETARY NAME AND DOSAGE FORM

IBECOL (capsule)

COMPOSITION

Each capsule contains: Active ingredients: Cascara sagrada (*Rhamnus purshianus*) 250 mg, Liquorice root (*Glycyrrhiza glabra*) 170 mg, *Aloe ferox* 75 mg, Ginger root 5 % extract (*Zingiber officinale*) 25 mg and Fennel seed powder (*Foeniculum vulgare*) 25 mg.

Other ingredients (excipients): Magnesium stearate, microcrystalline cellulose.

*Capsules are free of lactose, sugar, gluten and preservatives.

PHARMACOLOGICAL CLASSIFICATION

D 32.2 Other.

Discipline: Western herbal.

INDICATIONS

Ibecol is used for relief from various digestive complaints like occasional constipation, digestive discomfort, gas and bloating. This is based on traditional use only.

CONTRA-INDICATIONS

Do not use this medicine if you are hypersensitive (allergic) to any of the ingredients in the formulation or to celery, carrot or mugwort; or if you are pregnant or breastfeeding. Children younger than 12 years with constipation should not be treated with this medicine unless under medical supervision. Avoid this medicine if you suffer from diarrhoea, intestinal ulcers or obstruction, severe haemorrhoids, rectal bleeding, undiagnosed gastro-intestinal or abdominal disorder (or if appendicitis is suspected), anaemia, hypertension, congestive heart failure or if you had recent surgery.

WARNINGS AND SPECIAL PRECAUTIONS

If you suffer from any serious ailments or conditions (such as hypertension or diabetes); or if you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

- Overuse of stimulant laxatives can lead to dependency and decreased bowel function. Do not use continuously for more than two weeks without consulting your healthcare provider.
- Chronic use of laxatives may also lead to excessive loss of potassium or other electrolytes.
- This medicine might alter blood sugar levels. Please monitor blood sugar levels more frequently while taking this medication.
- This medicine might also slow blood clotting and should be used cautiously with any other blood thinning medication. Discontinue use two weeks prior to any scheduled surgery.
- No studies on the effect on the ability to drive and use machines have been performed. Please exercise care when driving or operating machinery until you know how it affects you.
- Porphyria: Safety has not been established.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

PREGNANCY AND LACTATION

Safety has not been established. If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

INTERACTIONS

If you are taking other medicines regularly, including complementary or traditional medicines, or start taking any additional medicines while taking this medicine, consult your healthcare provider for advice. If you are taking herbs and supplements that may increase the risk of bleeding (such as garlic), anticoagulant or antiplatelet medication (such as aspirin, warfarin, heparin or clopidogrel) and/or non-steroidal anti-inflammatory medications (such as ibuprofen or naproxen), please check with your healthcare provider before taking this medicine. This medicine might also affect the effectiveness of oral contraceptives and can cause hormonal imbalances. Taking this product with other medicine that increase potassium excretion such as watertablets, oral corticosteroids, sevoflurane, thyroid hormones, digoxin, zidovudine, etc. might decrease potassium in the body too much and increase risk of side effects. Low potassium can also affect digoxin levels and contaminant use should be avoided.

DOSAGE AND DIRECTIONS FOR USE

Take one capsule twice a day with meals and a glass of water, or as directed by your healthcare provider. Do not use continuously for more than two weeks without consulting your healthcare provider. If you still experience constipation after two weeks of using this product, consult your healthcare provider.

SIDE EFFECTS

Side effects can include abdominal cramps, diarrhoea and vomiting. Chronic use of laxatives may lead to excessive loss of potassium or other electrolytes and can also cause dependence on stimulant laxatives for bowel movement. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, discontinue use immediately and consult your doctor, pharmacist or other healthcare provider for advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

No known symptoms of overdose. Treatment is symptomatic and supportive.

IDENTIFICATION

Clear capsule filled with greenish-brown powder.

PRESENTATION

30 or 60 capsules are packed in a plastic container.

STORAGE INSTRUCTIONS

Store all medicines out of reach of children. Store in a cool dry place below 25 °C and keep away from direct sunlight. Keep the container tightly closed.

REGISTRATION NUMBER

To be allocated.

NAPPI CODE

30's: 719792002

60's: 719792003

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE

Alveta Healthcare (Pty) Ltd, 18 Greenwich Grove, Station Road, Rondebosch, 7700. Company registration number: 2004/021899/07. Pharmacy audit number: Y53008.

DATE OF PUBLICATION OF THE PACKAGE INSERT

30 September 2013

SKEDULERINGSSTATUS SO

HANDELSMERKNAAM EN DOSEERVORM

IBECOL (kapsule)

SAMESTELLING

Elke kapsule bevat: Aktiewe bestanddele: Cascara sagrada (*Rhamnus purshianus*) 250 mg, Licorice wortel (*Glycyrrhiza glabra*) 170 mg, *Aloe ferox* 75 mg, Gemmerwortel 5% uittreksel (*Zingiber officinale*) 25 mg en Vinkelsaad poeier (*Foeniculum vulgare*) 25 mg.

Onaktiewe bestanddele: Magnesium steeraat, mikrokristallyne sellulose.

*Kapsules bevat geen laktose, suiker, glutteen of preserveermiddels nie.

FARMAKOLOGIESE KLASIFIKASIE

D32.2 Ander.

Dissipline: Westerse kruie.

INDIKASIES

IBecol word gebruik om 'n verskeidenheid spysverteringsprobleme, soos toevallige konstipasie, abdominale ongemak, winde en opgeblaseheid te verlig. Hierdie is slegs gebaseer op tradisionele gebruik.

KONTRA-INDIKASIES

Vermay as jy hipersensitief (allergies) is vir enige van die bestanddele in die formule of vir seldery, wortel en mugwort; of as jy swanger is of borsvoed. Hierdie medisyne is nie geskik vir kinders onder die ouderdom van 12 jaar vir konstipasie nie, behalwe onder die toesig van 'n geneesheer.

Moenie gebruik indien jy diarree, intestinale ulkus of obstruksie, erge aambeie, rektale bloeding, ongediagnoseerde gastro-intestinale of abdominale probleme, anemia, hipertensie of indien jy onlangs sjirurgie ondergaan het nie.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

As jy enige voorgeskrewe medikasie gebruik of aan enige ernstige siektes of toestand (soos bv. hipertensie en diabetes) ly, raadpleeg jou geneesheer voordat jy hierdie medisyne begin gebruik.

- Gereelde gebruik kan lei tot afhanklikheid en verlies aan dermfunksie. Moenie vir langer as twee weke aaneen gebruik sonder om 'n geneesheer te raadpleeg nie.
- Kroniese gebruik van lakseermiddels kan lei tot oormatige verlies van kalium en ander elektroliete.
- Hierdie medisyne kan moontlik bloedsuikervlakke beïnvloed. Monitor jou bloedsuikervlakker meer gereeld indien jy hierdie medikasie gebruik.
- Hierdie medisyne kan ook moontlik bloedstolling vertraag en moet met sorg gebruik word in pasiënte wat enige ander bloedverduunningsmedikasie gebruik. Staak gebruik ten minste twee weke voor enige beplande sjirurgie.
- Geen studies is gedoen om die effek wat die medisyne het op bestuur en die gebruik van masjinerie vas te stel nie. Wees asseblief versigtig wanneer jy bestuur of masjinerie gebruik totdat jy weet hoe die medisyne jou beïnvloed.
- Porfirie: Veiligheid is nie vasgestel nie.

Voedingsaanvullings moet nie 'n gebalanseerde dieët vervang nie. Moenie die aanbevole dosis oorskry sonder om 'n geneesheer te raadpleeg nie.

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie. Raadpleeg jou geneesheer as jy swanger is of borsvoed voordat jy hierdie medisyne gebruik.

INTERAKSIES

As jy ander medisyne gereeld gebruik, insluitend aanvullende (komplimentêre) of tradisionele medisyne, of as jy enige addisionele medisyne begin neem terwyl jy hierdie medisyne gebruik, raadpleeg jou geneesheer vir raad. Indien jy kruie of aanvullings gebruik wat die risiko van bloeding verhoog (soos knoffel), stollingsteemiddels of bloedverduunningsmedikasie (soos aspirien, warfarien, heparien of klopidogrel) of nie-steroidale anti-inflammatoriese medikasie (soos ibuprofen of naproksen), raadpleeg eers 'n geneesheer voordat jy die medikasie gebruik aangesien hierdie medisyne ook moontlik bloeding kan veroorsaak. Hierdie medisyne kan moontlik die effekwiteit van orale kontrasepsie beïnvloed en kan hormonale wanbalans veroorsaak. Indien hierdie medisyne gebruik word saam met ander medisyne wat ook kalium uitskeiding veroorsaak, soos bv. watertabelle, sistemiese kortikosteroïede, tiroksien, digoksien, zidovidien, ens., kan dit lei tot té lae vlakke van kalium. Lae kalium kan ook 'n invloed hê op digoksien en die gebruik van hierdie produk saam met digoksien moet vermy word.

DOSES EN GEBRUIKSAANWYSINGS

Neem een kapsule twee maal per dag na etes met 'n glas water, of soos jou geneesheer voorskryf. Moenie vir langer as twee weke aanenlopend gebruik sonder om 'n geneesheer te raadpleeg nie. Indien na twee weke nogsteeds hardlywig is, raadpleeg jou geneesheer.

NEWE-EFFEKTE

Nuwe-effekte sluit abdominale krampe, diarree en vormering in. Gereelde gebruik van lakseermiddels kan lei tot oormatige kalium en elektroliet verlies en kan ook afhanklikheid aan stimuleerende lakseermiddels vir opelyf veroorsaak. Sommige aangemelde nuwe-effekte is nie in hierdie voubiljet ingesluit nie. Indien jy enige onaangename nuwe-effekte ervaar of voel dat jou algemene gesondheid verswak, hou onmiddellik op om die medisyne te gebruik en kontak jou geneesheer.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING

Simptome van oordosering is onbekend. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

Deursigtige kapsule met 'n groenerige, bruin poeier.

AANBIEDING

30 of 60 kapsules is verpak in 'n plastiek houer.

BERGINGSAAWYSINGS

Berg alle medisyne buite bereik van kinders. Berg in 'n koel, droë plek onder 25 °C en hou weg van direkte sonlig. Hou die houer dig toe.

REGISTRASIE NOMMER

Sal toegeken word.

NAPPI KODE

30's: 719792002

60's: 719792003

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Alveta Healthcare (Pty) Ltd, Greenwich Grove 18, Station weg, Rondebosch, 7700. Maatskappy registrasie nommer: 2004/021899/07. Apteek oudit nommer: Y53008.

DATUM VAN VOUBILJET PUBLIKASIE

30 September 2013

Hierdie medisyne is nie deur die Medisyne Beheerraad geëvalueer nie.

Hierdie medisyne is nie bedoel om te diagnoseer, behandel, voorkom of enige siekte toestand te genees nie.