Claudia Law - Approved - 30.07.2021

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CUSTOMER APPROVAL

Ticket	2364
Customer	Nkunzi
Product	Mebestend PIL
Code	F71877
Flat Size	160 x 250 mm
Folded Size	160 x 31,25 mm
Pharma Code	94
Colours	Black (both sides)
Version No.	2
Date	29/7/21
Operator	Jane
AM approval	

PLEASE CHECK CAREFULLY...

...Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

Approved by	
Signature	
Date	

Lees hierdie pamflet sorgvuldig deur voordat u MEBESTEND begin neem. Selfs al het u die voorskrif net weer hervul of hierdie medisyne tevore gebruik. Die inligting in die vorige pamflet mag moontlik verander het. Raadpleeg u dokter of apteker indien u verdere vrae het. MEBESTEND is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander persone deel nie. Dit kan hulle benadeel, selfs al sou hulle dieselfde simptome as u ervaar.

1. SKEDULERINGSTATUS: S2

2. EIENDOMSNAAM EN DOSEERVORM:
MEBESTEND (Filmbedekte tablette)
Mebeverienhidrochloried

3. WAT MEBESTEND TABLETTE BEVAT:
Elke tablet bevat 135 mg van die aktiewe bestanddeel mebeverienhidrochloried.

Die ander bestanddele is: laktose monohidraat 100 mg, mikrokristallyne sellulose PH101, mikrokristallyne sellulose PH102, povidone K30, natriumstyselglikolaat, gesuiwerde talk en magnesiumstearaat. Filmbedekking: Opadry wit, hipromellose, titaandioksied, makrogol. Bevat suiker.

4. WAARVOOR MEBESTEND GEBRUIK WORD:
Dit werk op spasmas van die gladdespier van die spysverteringskanaal in. MEBESTEND tablette word vir primêre prikkelbare dikderm wat deur aanhoudende diarree, afwisselende hardlywigheid en diarree, buikpyn en opgeblase gevoel asook ongemaklikheid na 'n maaltyd gekenmerk word, gebruik. Dit word ook vir sekondêre prikkelbare dikderm wat 'n gevolg is van organiese letsels soos lokale enteritis, divertikulitis, spesifieke en nie-spesifieke inflammatoriese toestande in die spysverteringskanaal, gebruik.

5. VOORDAT U MEBESTEND TABLETTE NEEM:
Moenie MEBESTEND tablette neem:
- Indien u allergies is vir mebeverien, laktose of enige van die ander bestanddele van die tablet
- Indien u swanger is of beplan om swanger te raak
- Indien u borsvoed
- Indien u aan porfirie ly ('n metaboliese siektetoestand)

Neem spesiale sorg met MEBESTEND tablette:
- Indien u lewer- of nierprobleme het
- Indien u hartprobleme het

Neem van ander medisynes saam met MEBESTEND tablette:
Dit word nie verwag dat MEBESTEND ander medisyne wat u gebruik sal beïnvloed nie. Raadpleeg u apteker indien u onseker is oor interaksies met enige medisyne. Dit sluit medisyne in wat deur u dokter voorgeskryf is asook medisyne, insluitende kruie- en homeopatiese middels, wat u self gekoop het.

Indien u gereeld ander medisyne gebruik, insluitend komplimentêre of tradisionele medisyne, kan die gebruik van MEBESTEND tablette saam met hierdie medisyne ongewenste interaksies veroorsaak. Raadpleeg u dokter, apteker of ander gesondheidswerker vir advies.

Swangerskap en Borsvoeding:

Raadpleeg u dokter, apteker of ander gesondheids-werker vir advies indien u swanger is of u baba borsvoed terwyl u MEBESTEND gebruik.

Belangrike inligting omtrent sommige van die bestanddele van MEBESTEND:

Vertel u dokter indien u laktose-intolerant of intolerant vir ander suikers is.
MEBESTEND bevat laktose monohidraat. Stel u dokter in kennis alvorens u MEBESTEND neem indien u weet dat u laktose-intolerant is, of indien daar al tevore aan u gesê is dat u 'n suiker-intoleransie het.

6. HOE OM MEBESTEND TABLETTE TE NEEM:
Dit is baie belangrik dat u, u medisyne neem soos u dokter aan u voorgeskryf het. Raadpleeg u dokter of apteker indien u nie seker is nie.
- Sluk een tablet drie keer per dag, verkieslik voor etes.
- U dokter mag na 'n paar weke wanneer die gewenste effek verkry is die dosis geleidelik verminder.

Raadpleeg dokter of apteker indien u onder die indruk is dat die effek van MEBESTEND te sterk of te swak is.

Moenie medisyne wat aan u voorgeskryf is met ander persone deel nie.

Indien u meer MEBESTEND neem as wat u moes:
Ingeval van oordosering, raadpleeg u dokter of apteker. Indien albei nie beskikbaar is nie kontak die naaste hospitaal of vergiftingskontrole sentrum.

7. MOONTLIKE NEWE-EFFEKTE:
MEBESTEND kan newe-effekte hê.

U mag duiseligheid, hoofpyn en slapeloosheid ervaar.

Daar is ook 'n moontlikheid van gastro-intestinale versteurings of hipersensitiwiteitsreaksies (swelling van u gesig, lippe of tong; 'n rooi veluitslag, jeukerigheid en opvlamming).

Indien u aan een van hierdie newe-effekte ly of enige effekte opmerk wat nie in hierdie voubiljet genoem word nie, moet u dit aan u dokter of apteker rapporteer.

Nie al die newe-effekte wat vir MEBESTEND gerapporteer is, is in hierdie voubiljet ingesluit nie. Raadpleeg asseblief u dokter, apteker of ander gesondheidswerker vir advies indien u algemene gesondheid agteruitgaan terwyl u MEBESTEND neem.

8. STOOR EN WEGGOOI VAN MEBESTEND TABLETTE:
Stoor tablette buite bereik en sig van kinders. Bewaar benede 30 °C. Beskerm teen lig. Stoor in 'n lugdigte houers. Moenie hierdie medisyne na die vervaldatum wat op die etiket en stulpstroke aangedui word, neem nie. Neem alle ongebruikte medisyne na u apteker. Moenie ongebruikte medisyne in afvoerpype of rioolsisteme weggooi nie (bv. toilette).

9. AANBIEDING VAN MEBESTEND TABLETTE:
Filmbedekte tablette word in ondeursigtige, wit, HDPE securitainers met 20, 100 en 500 tablette verpak. Alternatiewelik word die tablette in PVC/Aluminium stulpstroke met 10 tablette per strokie in eenheidskartonne van 20 en 100 tablette verpak.

10. IDENTIFIKASIE VAN MEBESTEND TABLETTE:
Wit, ronde filmbedekte tablette.

11. REGISTRASIENOMMER:
32/11.2/0598

12. NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
Trinity Pharma (Pty) Ltd.
106 16de Straat 106, Gebou 2, Midrand, 1686.

13. DATUM VAN PUBLIKASIE VAN DIE INLIGTINGSPAMFLET:
19 Julie 2001

Vir professionele inligting voubiljet:
www.trinitypharma.co.za

TRINITY PHARMA F71877

Please read this leaflet carefully before you start to take MEBESTEND, even if you have just refilled the prescription or used this medicine before. The information in the previous leaflet may have changed. If you have further questions, please ask your doctor or pharmacist. MEBESTEND has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. SCHEDULING STATUS: S2

2. PROPRIETARY NAME AND DOSAGE FORM:
MEBESTEND (Film-coated tablets)
Mebeverine hydrochloride

3. WHAT MEBESTEND TABLETS CONTAIN:
Each tablet contains 135 mg of the active ingredient mebeverine hydrochloride.

The other ingredients are: lactose monohydrate 100 mg, microcrystalline cellulose PH101, microcrystalline cellulose PH102, povidone K30, sodium starch glycollate, purified talc, magnesium stearate.
Film coating: Opadry white, hypromellose, titanium dioxide, macrogol.
Contains sugar.

4. WHAT MEBESTEND IS USED FOR:
It acts on smooth muscle spasms of the gastrointestinal tract. MEBESTEND tablets are used for primary irritable colon characterised by persistent diarrhoea, alternating constipation and diarrhoea, abdominal pain and feeling bloated and uncomfortable after eating. It is also used for secondary irritable colon due to organic lesions such as regional enteritis, diverticulitis, specific and non-specific inflammatory conditions of the gastrointestinal tract.

5. BEFORE TAKING MEBESTEND TABLETS:
Do not take MEBESTEND tablets if:
- you are allergic to mebeverine, lactose or any of the other tablet ingredients
- you are pregnant or planning to become pregnant
- you are breastfeeding
- you have porphyria (a metabolism problem)

Take special care with MEBESTEND tablets if:
- you have liver or kidney problems
- you have heart problems

Taking other medicines with MEBESTEND tablets:
MEBESTEND is not expected to affect any other medicines that you may be taking. If you are unsure about interactions with any medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicines you have bought for yourself, including herbal and homeopathic remedies.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of MEBESTEND tablets with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby while taking MEBESTEND, please consult your doctor, pharmacist or other health care professional for advice.

Important information about some of the ingredients of MEBESTEND:

Tell your doctor if you are lactose-intolerant or intolerant to other sugars.
MEBESTEND contains lactose monohydrate. If you know you are lactose-intolerant, or if you have been told that you have intolerance to any other sugars, talk to your doctor before taking MEBESTEND.

6. HOW TO TAKE MEBESTEND TABLETS:
It is very important that you take your medicine as your doctor tells you. You should check with your doctor or pharmacist if you are not sure.
- Swallow one tablet three times a day preferably before meals.
- After a few weeks when the desired effect has been obtained, your doctor may gradually reduce the dosage.

If you have the impression that the effect of MEBESTEND is too strong or too weak, talk to your doctor or pharmacist.

Do not share medicines prescribed for you with others.

If you take more MEBESTEND than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

7. POSSIBLE SIDE EFFECTS:
MEBESTEND may cause side effects.

You might experience occurrences of dizziness, headache and sleeplessness.

There may also be a possibility of gastrointestinal disorders or hypersensitivity reactions (swelling of your face, lips or tongue; a red skin rash, itching, and flares).

If you suffer from any of these side effects or notice any effects not mentioned in this leaflet, please tell your doctor or pharmacist.

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

8. STORAGE AND DISPOSAL OF MEBESTEND TABLETS:
Keep tablets out of the reach and sight of children. Store below 30 ºC. Protect from light. Keep in airtight containers. Do not take this medicine after the expiry date shown on the label and blister. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

9. PRESENTATION OF MEBESTEND TABLETS:
Film-coated tablets are packed into opaque, white HDPE securitainers of 20, 100 and 500 tablets. Alternatively the tablets are packed in PVC/Aluminium blisters containing 10 tablets per strip in unit cartons of 20 and 100 tablets.

10. IDENTIFICATION OF MEBESTEND TABLETS:
White, round, film-coated tablets.

11. REGISTRATION NUMBER:
32/11.2/0598

12. THE NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:
Trinity Pharma (Pty) Ltd.
106 16th Road, Building 2, Midrand, 1686.

13. THE DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:
19 July 2001

For professional information leaflet:
www.trinitypharma.co.za

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