SCHEDULING STATUS **S2**

PROPRIETARY NAME AND DOSAGE FORM

MEDINOR™ 1,5 mg tablet

COMPOSITION

Active ingredient:

Each tablet contains 1,5 mg levonorgestrel.

Inactive ingredients:

Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, povidone.

Contains sugar: lactose monohydrate.

PHARMACOLOGICAL CLASSIFICATION

A 21.8.2 Progesterones with or without oestrogen

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

Levonorgestrel is a progesterone and acts as a contraceptive by inhibiting ovulation and preventing the nidation of a fertilised ovum in the uterine mucosa.

Pharmacokinetic properties:

Oral bioavailability of levonorgestrel is approximately 100 %. In the plasma it is strongly bound to SHBG (sex hormone binding globulin). Levonorgestrel is eliminated metabolically via the kidney (60 to 80 %) and liver (40 to 50 %).

After oral administration of 1,5 mg levonorgestrel the plasma terminal half-life is estimated to be 43 hours. The maximal plasma concentration (approximately 40 nmol/ℓ) is reached within 3 hours. Levonorgestrel is hydroxylated in the liver and the metabolites are excreted as glucoronide conjugates.

INDICATIONS

MEDINOR is indicated for the prevention of pregnancy within 72 hours of unprotected sexual intercourse or the recognisable failure of mechanical methods.

MEDINOR is intended for emergencies only and is completely unsuitable for regular contraception. Its reliability is not as high as that of the familiar "pill", which is taken for at least 21 days of the menstrual cycle.

CONTRAINDICATIONS

- Hypersensitivity to levonorgestrel or to any of the inactive ingredients of MEDINOR (see COMPOSITION).
- Pregnancy: MEDINOR should not be used if there is a possibility that pregnancy already exists, e.g. if unprotected sexual intercourse has already taken place in the same cycle or if the last menstrual period failed to occur (see PREGNANCY AND LACTATION).
- MEDINOR should not be given to patients with undiagnosed vaginal bleeding, or to those with a history, or current high risk of arterial disease.
- Severe hepatic impairment.
- Women with hormone-dependent neoplasms.

- Active trophoblastic disease.
- The repeated use of MEDINOR within a monthly cycle is to be avoided, since it constitutes undesirable hormonal stress and may result in severe cycle disturbances.
- Porphyria.
- MEDINOR is not recommended for women who are at risk of an ectopic pregnancy.

WARNINGS AND SPECIAL PRECAUTIONS

Pregnancy, puerperium and perinatal conditions:

Patients who become pregnant despite emergency contraception should be carefully evaluated for ectopic pregnancy.

Therefore, MEDINOR is not recommended for patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy).

The effect of MEDINOR on the conceptus in the event of a failure to prevent conception is not definitely known. Therefore, a pregnancy test must be performed if there is any doubt.

MEDINOR is intended for emergencies only and is completely unsuitable for regular contraception. Its reliability is not as high as that of the familiar "pill", which is taken for at least 21 days of the menstrual cycle.

MEDINOR should not be used diagnostically for pregnancy testing and should not be given in missed or incomplete abortion.

The use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases.

Endocrine disorders:

The next menstrual period may occur earlier or later than usual. A healthcare professional should be consulted 3 weeks after taking MEDINOR regardless of whether bleeding has occurred or not.

Other:

MEDINOR should be used with caution in women with:

- Malabsorption syndromes
- Liver dysfunction
- Functional ovarian cyst
- Diabetes mellitus
- Hypertension
- Migraine
- Thromboembolic disorder
- Epilepsy
- Asthma
- Cardiac and renal impairment
- Depression

Lactose:

MEDINOR contains lactose (see COMPOSITION). Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take MEDINOR.

Effects on ability to drive and use machines:

MEDINOR may cause drowsiness and dizziness. Patients should be advised not to drive or operate machines until it is established that their ability to perform such activities is not affected. Patients should be advised to use caution when driving a car or operating hazardous machinery until they are reasonably certain that their performance is not affected by MEDINOR.

INTERACTIONS

Interactions with other medicines:

The metabolism of MEDINOR is enhanced by the concomitant use of liver enzyme inducers: anticonvulsants (phenobarbitone, phenytoin, primidone and carbamazepine); rifabutin, rifampicin, griseofulvin, ritonavir, *Hypericum perforatum* (St John's wort).

The efficacy of MEDINOR may be decreased in cases of concomitant intake of the above mentioned medicines.

PREGNANCY AND LACTATION

Pregnancy:

MEDINOR is contraindicated in pregnancy (see CONTRAINDICATIONS).

Lactation:

MEDINOR is secreted into breast milk and breastfeeding should not occur within 6 hours of administration of MEDINOR (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Take one MEDINOR 1,5 mg tablet as soon as possible, preferably within 12 hours, but not later than 72 hours after unprotected sexual intercourse.

The earlier MEDINOR is used, the more effective it is. Even extremely high doses of hormone can no longer prevent pregnancy once a fertilised ovum has become implanted in the uterine mucosa.

All further unprotected sexual intercourse must be avoided until the next menstrual period; until then, only mechanical and/or chemical methods (condom, foam and pessary) of contraception may be used.

SIDE EFFECTS

Immune system disorders:

Less frequent: Anaphylaxis or anaphylactoid reactions.

Endocrine disorders:

Frequent: Premenstrual syndrome-like symptoms, altered menstrual cycles or irregular menstrual bleeding, spotting.

Less frequent: Cushing's syndrome, hot flushes.

Frequency unknown: Certain progesterones such as MEDINOR may have an adverse effect on serum lipids.

Metabolism and nutrition disorders:

Frequent: Changes in weight, oedema, hyperglycaemia.

Frequency unknown: Changes in appetite, fluid retention.

Psychiatric disorders:

Frequent: Nervousness, mood changes.

Less frequent: Mental depression.

Nervous system disorders:

Frequent: Drowsiness, dizziness, headache.

Less frequent: Insomnia.

Vascular disorders:

Less frequent: Adrenal suppression or insufficiency or hypotension; thromboembolism or thrombus formation.

Gastrointestinal disorders:

Frequent: Abdominal pain or cramping, diarrhoea, nausea, vomiting.

Frequency unknown: Gastrointestinal disturbances.

Hepato-biliary disorders:

Less frequent: Alterations in liver function tests, jaundice.

Skin and subcutaneous tissue disorders:

Less frequent: Acne, melasma or chloasma, allergic skin reactions, hair loss, hirsutism.

Frequency unknown: Urticaria, fever.

Musculoskeletal, connective tissue and bone disorders:

Frequency unknown: Loss of bone mineral density, osteoporosis, osteoporotic fracture.

Reproductive system and breast disorders:

Frequent: Breast tenderness.

Less frequent: Galactorrhoea, breast changes including gynaecomastia, changes in libido.

General disorders and administrative site conditions:

Frequent: Fatigue.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

(See SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS).

Treatment is symptomatic and supportive.

IDENTIFICATION

White, round, biconvex tablet with the code “NL 1.5” engraved on one side.

PRESENTATION

1 tablet in PVC complex (PVC/PE/PVDC orange) and aluminium foil blister strip. The blister strip is enclosed in an outer cardboard carton.

STORAGE INSTRUCTIONS

Store in a cool place at or below 25 °C.

Protect from moisture and light.

Keep the blister strip in the outer carton until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER

44/21.8.2/0810

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Actor Pharma (Pty) Ltd[1]

Unit 7, Royal Palm Business Estate

646 Washington Street

Halfway House, Midrand, 1685

Gauteng, South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT

26 November 2015

TM – MEDINOR is a trademark of Actor Pharma (Pty) Ltd

[1] Company Registration number: 2008/008787/07

SKEDULERINGSTATUS **S2**

EIENDOMSNAAM EN DOSEERVORM

MEDINOR™ 1,5 mg tablet

SAMESTELLING

Aktiewe bestanddeel:

Elke tablet bevat 1,5 mg levonorgestrel.

Onaktiewe bestanddele:

Kolloïdale anhidriese silika, laktosemonohidraat, magnesiumstearaat, mieliestysel, povidoon.

Bevat suiker: laktosemonohidraat.

FARMAKOLOGIESE KLASSIFIKASIE

A. 21.8.2 Progesterone met of sonder estrogene

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe:

Levonorgestrel is ’n progesteroon en werk as ’n voorbehoedmiddel deur ovulasie te onderdruk en inplanting van ’n bevrugte eiersel in die baarmoederwand te voorkom.

Farmakokinetiese eienskappe:

Die orale biobeskikbaarheid van levonorgestrel is ongeveer 100 %. In die plasma is dit sterk aan SHBG (sekshormoon bindende globulien) gebind. Levonorgestrel word metabolies deur die niere (60 to 80 %) en lewer (40 to 50 %) uitgeskei.

Die terminale halfleeftyd in plasma na orale toediening van 1,5 mg levonorgestrel word op 43 uur geskat. Die maksimum plasmakonsentrasie (ongeveer 40 nmol/ℓ) word binne 3 uur bereik. Levonorgestrel word in die lewer gehidroksileer en die metaboliete word as glukoroniede uitgeskei.

INDIKASIES

MEDINOR is aangedui vir die voorkoming van swangerskap binne 72 uur na onbeskermde seksuele omgang of die herkenbare faling van meganiese metodes.

MEDINOR is slegs bedoel vir noodgevalle en is heeltemal onvanpas as voorbehoedmiddel. Die betroubaarheid is nie so hoog soos dié van die bekende "pil" nie, wat vir minstens 21 dae van die menstruele siklus gedrink word.

KONTRAINDIKASIES

- Hipersensitiwiteit teenoor levonorgestrel of teenoor enige van die onaktiewe bestanddele van MEDINOR (kyk SAMESTELLING).
- Swangerskap: MEDINOR moet nie gebruik word as daar ’n moontlikheid is dat daar reeds ’n swangerskap is nie, bv. indien onbeskermde seksuele omgang reeds in dieselfde siklus plaasgevind het of indien die laaste menstruasie nie voorgekom het nie (kyk SWANGERSKAP EN BORSVOEDING).
- MEDINOR moet nie gegee word aan pasiënte met ongediagnoseerde vaginale bloeding of diegene met ’n geskiedenis van of huidige hoë risiko vir arteriële siektes nie.
- Erge swak lewerfunksie.
- Vroue met hormoonafhanklike neoplasmas.
- Aktiewe trofoblastiese siekte.
- Die herhaalde gebruik van MEDINOR binne ’n maandelikse siklus moet vermy word, aangesien dit ongewenste hormonale stres tot gevolg het en tot ernstige siklus versteurings kan lei.
- Porfirie.

- MEDINOR word nie aanbeveel vir vroue wat ’n ektopiese swangerskap het nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS

Swangerskap, puerperium en perinatale toestande:

Pasiënte wat ten spyte van noodkontrasepsie swanger word, moet noukeurig vir ektopiese swangerskap geëvalueer word.

Daarom word MEDINOR nie aanbeveel vir pasiënte met ’n risiko van ektopiese swangerskap nie (vorige geskiedenis van salpingitis of ektopiese swangerskap).

Die effek van MEDINOR op konsepsie in die geval van mislukking om konsepsie te voorkom, is nie heeltemal bekend nie. Daarom moet ’n swangerskapstoets gedoen word indien daar enige twyfel is.

MEDINOR is slegs bedoel vir noodgevalle en is heeltemal onvanpas as voorbehoedmiddel. Die betroubaarheid is nie so hoog soos dié van die bekende "pil" nie, wat vir minstens 21 dae van die menstruele siklus gedrink word.

MEDINOR moet nie diagnosties vir die toets van swangerskap gebruik word nie en moet nie met mislukte of onvolledige aborsies gegee word nie.

Die gebruik van noodvoorbehoeding vervang nie die nodige voorsorgmaatreëls teen seksueel oordraagbare siektes nie.

Versteurings van endokrienstelsel:

Die volgende menstruasie kan vroeër of later as gewoonlik voorkom. ’n Gesondheidsorgdeskundige moet 3 weke na die gebruik van MEDINOR geraadpleeg word, ongeag of bloeding voorgekom het al dan nie.

Ander:

MEDINOR moet versigtig gebruik word deur pasiënte met:

- Sindroom van wanabsorpsie
- Lewerdisfunksie
- Funksionele ovariumsist
- Diabetes mellitus
- Hipertensie
- Migraine
- Trombo-emboliese versteuring
- Epilepsie
- Asma
- Swak hart- en nierfunksie
- Depressie

Laktose:

MEDINOR bevat laktose (kyk SAMESTELLING). Pasiënte met die skaars oorerflike probleem van onverdraagbaarheid van galaktose, die Lapp-laktase tekort of wanabsorpsie van glukose/galaktose, moet nie MEDINOR gebruik nie.

Effek op vermoë om motor te bestuur en masjinerie te gebruik:

MEDINOR kan lomerigheid en duiseligheid veroorsaak. Pasiënte moet aangeraai word om nie ’n voertuig te bestuur of masjiene te hanteer nie totdat dit vasgestel is dat hul vermoë om sulke aktiwiteite uit te voer nie geraak word nie. Pasiënte moet aangeraai word om versigtig te wees wanneer ’n motor bestuur of gevaarlike masjinerie bedryf word totdat hulle redelik seker is dat hul optrede nie deur MEDINOR aangetas word nie.

INTERAKSIES

Interaksies met ander medisyne:

Die metabolisme van MEDINOR word versterk deur die gepaardgaande gebruik van lewerensieminduseerders: antikonvulsante (fenobarbitoon, fenitoïen, primidoon en karbamasepien); rifabutien, rifampisien, griseofulvien, ritonavir, *Hypericum perforatum* (Johanneskruid – “St John's wort”). Die effektiwiteit van MEDINOR kan deur gelyktydige inname van bogenoemde medisyne verlaag word.

SWANGERSKAP EN BORSVOEDING

Swangerskap:

MEDINOR is teenaangedui tydens swangerskap (kyk KONTRAINDIKASIES).

Borsvoeding:

MEDINOR word in borsmelk uitgeskei en borsvoeding moet nie binne 6 uur na toediening van MEDINOR gegee word nie (kyk KONTRAINDIKASIES).

DOSIS EN GEBRUIKSAANWYSINGS

Drink een MEDINOR 1,5 mg tablet so gou as moontlik, verkieslik binne 12 uur, maar nie later as 72 uur na onbeskermde seksuele omgang nie.

Hoe vroeër MEDINOR gebruik word, hoe meer doeltreffend is dit. Selfs uiters hoë dosisse hormone kan swangerskap nie meer voorkom nadat ’n bevrugte eiersel in die baarmoederwand ingeplant is nie.

Alle verdere onbeskermde seksuele omgang moet tot die volgende menstruasie vermy word; tot dan kan slegs meganiese en/of chemiese metodes (kondoom, skuim en pessarium) van voorbehoeding gebruik word.

NEWE-EFFEKTE

Versteurings van die immuunstelsel:

Minder dikwels: Anafilakse waaronder anafilaktoïede reaksies.

Versteurings van endokrienstelsel:

Dikwels: Simptome soos van premenstruele sindroom, veranderde menstruele siklusse of onreëlmatige menstruele bloeding, kolle.

Minder dikwels: Cushing se sindroom, warm gloede.

Frekwensie onbekend: Sekere progesterone soos MEDINOR kan ’n nadelige invloed op serumlipiede hê.

Versteurings in metabolisme en voeding:

Dikwels: Gewigsveranderinge, edeem, hiperglukemie.

Frekwensie onbekend: Veranderinge in eetlus, vloeistofretensie.

Psigiatriese versteurings:

Dikwels: Senuagtigheid, wisselende buie.

Minder dikwels: Verstandelike depressie.

Versteurings van die senustelsel:

Dikwels: Lomerigheid, duiseligheid, hoofpyn.

Minder dikwels: Slaaploosheid.

Vaskulêre versteurings:

Minder dikwels: Adrenale onderdrukking of ontoereikendheid of hipotensie; trombo-embolisme of vorming van trombusse.

Gastro-intestinale versteurings:

Dikwels: Buikpyn of -krampe, diarree, naarheid, braking.

Frekwensie onbekend: Gastro-intestinale versteurings.

Hepatobiliêre versteurings:

Minder dikwels: Veranderings in waardes van lewerfunksietoetse, geelsug.

Versteurings van die vel en subkutane weefsel:

Minder dikwels: Aknee, melasma of chloasma, allergiese velreaksies, haarverlies, hirsutisme.

Frekwensie onbekend: Urtikarie, koors.

Versteurings van die muskuloskeletale stelsel, bindweefsel en skeletbene:

Frekwensie onbekend: Verlies van beenmineraaldigtheid, osteoporose, osteoporotiese fraktuur.

Versteurings van voortplantingstelsel en borste:

Dikwels: Teerheid van die borste.

Minder dikwels: Galaktorree, veranderinge aan die borste waaronder ginekomastie, veranderinge in libido.

Algemene versteurings en by die plek van toediening:

Dikwels: Moegheid.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

Kyk NEWE EFFEKTE en WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS.

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

Wit, ronde, bikonvekse tablet met die kode “NL 1.5” op die een kant gedruk.

AANBIEDING

1 tablet in PVC-kompleks (PVC/PE/PVDC oranje) en stulpstrook van aluminium. Die stulpstrook is in ’n buitenste karton.

BEWARINGSINSTRUKSIES

Bewaar op ’n droë plek by of onder 25 ºC.

Beskerm teen vog en lig.

Hou die stulpstrook in die karton totdat dit benodig word.

HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER

44/21.8.2/0810

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Actor Pharma (Edms) Bpk[1]

Eenheid 7, Royal Palm Sake Landgoed

Washingtonstraat 646

Halfway House, Midrand, 1685

Gauteng, Suid-Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

26 November 2015

TM - MEDINOR is ’n handelsmerk van Actor Pharma (Edms) Bpk

[1] Maatskappyregistrasienommer: 2008/008787/07

MEDN/PI/01/01.2019