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	ARTWORK DETAILS		SPECIFICATION DETAILS	
	<p>We ask you to check fully and sign below. Every care is taken to ensure correctness. We cannot be held responsible for mistakes if passed by you.</p> <p>Please mark clearly any changes you require and return the original visual to us. (Colours on the visual are representative and not exact colour matches).</p> <p>We will re-proof by return unless instructed otherwise. Major alterations from the original copy are chargeable as 'Author's Corrections'.</p> <p>CLO641ISSUE 8</p>	Customer	Actavis (UK) Ltd	Previous Version
Product Name		CYCLOGEST 200MG X 15S (SOUTH AFRICA)	Pharmacode No	n/a
Item Code		50943832	Material	50gsm Opaque
Our Ref		SO50641	Flat Size	210 x 148
Proof No		One	Fold Size	148 x 27
Date		27/04/2018	View Panel	PHARMACODE TO VIEW
ARTWORK APPROVED		<input type="checkbox"/>	Fold Detail	PARALLEL
AMENDMENTS REQUIRED		<input type="checkbox"/>	Packing Details	Shrinkwrapped in trays
			Colours Front	BLACK, P.GREEN
			Colours Back	BLACK, P.GREEN

	Specification and Artwork approved for printing by
	SIGNATURE
	PRINT DATE

CYCLOGEST®
Progesterone



SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:
CYCLOGEST® 200 mg (pessaries)

COMPOSITION:
Each pessary, suitable for vaginal insertion, contains 200 mg progesterone Ph.Eur.

PHARMACOLOGICAL CLASSIFICATION:
A 21.8.2 Progesterones with or without oestrogens

PHARMACOLOGICAL ACTION:
CYCLOGEST 200 mg (progesterone) is a natural progestogen. Progesterone released during the luteal phase of the menstrual cycle leads to the development of a secretory endometrium. Abrupt decline in the release of progesterone from the corpus luteum at the end of the cycle is the main determinant of the onset of menstruation. If the duration of the luteal phase is artificially lengthened, either by sustaining luteal function or by treatment with progesterone, decidual changes in the endometrial stroma similar to those seen in early pregnancy can be induced. The oestrogen-induced maturation of the human vaginal epithelium is modified towards the condition of pregnancy by the action of progesterone. Progesterone is important for the maintenance of pregnancy as it suppresses menstruation and uterine contractility. Recent evidence has revealed that in controlled clinical studies CYCLOGEST 200 mg was not shown to be more efficacious than placebo in the treatment of premenstrual syndrome.

INDICATIONS:
CYCLOGEST 200 mg is indicated for the supplementation of insufficient secretion of progesterone in women participating in fertilisation programmes.

CONTRAINDICATIONS:
Undiagnosed vaginal bleeding.
A history of thromboembolic disorders.

WARNINGS AND PRECAUTIONS:
Progesterone is metabolised in the liver and should be used with caution in patients with hepatic dysfunction. CYCLOGEST 200 mg contains the hormone progesterone which is present in significant concentrations in women during the second half of the menstrual cycle and during pregnancy. This should be borne in mind when treating patients with conditions that may be hormone-sensitive. Unless progestogens are being used as part of the management of breast carcinoma they should not be given to patients with these conditions.

USE IN PREGNANCY AND LACTATION:
Progesterone is a natural hormone and is not expected to have adverse effects, but no evidence is available to this effect.

DOSAGE AND DIRECTIONS FOR USE:
The dosage of CYCLOGEST 200 mg is 200 mg inserted into the vagina daily but can be increased to 400 mg twice daily.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Progesterones should be used with caution in patients with cardiovascular or renal impairment, diabetes mellitus, asthma, epilepsy, migraine or other conditions which may be aggravated by fluid retention. They should be used with care in persons with

a history of mental depression. Menstruation may occur earlier than expected or, more rarely, menstruation may be delayed. Leakage of the pessary base may occur. Side effects of progesterone may include gastro-intestinal disturbances, acne, fluid retention or oedema, mass gain, allergic skin rashes or urticaria, mental depression, breast changes including discomfort or less frequently gynaecomastia and changes in libido. Alterations in liver function tests have been reported and jaundice has been reported less frequently.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Overdosage may produce euphoria or dysmenorrhoea. Treatment is symptomatic and supportive.

IDENTIFICATION:
Off-white pessaries.

PRESENTATION:
Cardboard cartons containing 15 pessaries, packed in blister strips of five.

STORAGE INSTRUCTIONS:
Store at or below 25 °C in a dry place.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
Z/21.8.2/294

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Actavis Pharma (Pty) Ltd.
Maxwell Office Park
Magwa Crescent West
Waterfall City
Midrand
Gauteng
2090

DATE AND PUBLICATION OF THIS PACKAGE INSERT:
Date of registration: 22 February 1994
Revised: 02 March 2015

NAMIBIA:
Scheduling: NS1
Registration number: 04/21.8.2/1213

BOTSWANA:
Scheduling: NS2
Registration number: BOT1302281

AAAK4375

CYCLOGEST®

Progesterone



SKEDULERINGSSTATUS: S4

EIENDOMSNAAM EN DOSEERVORM:
CYCLOGEST® 200 mg (setpille)

SAMESTELLING:
Elke setpil, geskik vir vaginale toediening, bevat 200 mg progesteron Ph Eur.

FARMAKOLOGIESE KLASSIFIKASIE:
A 21.8.2 Progesteron met of sonder estrogene

FARMAKOLOGIESE WERKING:
CYCLOGEST 200 mg (progesteron) is 'n natuurlike progestogeen. Progesteron wat gedurende die luteale fase van die menstruele siklus vrygestel word, lei tot die vorming van 'n sekretoriese endometrium. 'n Skielike afname in die vrystelling van progesteron, van die korpus luteum aan die einde van die siklus, is die hoofbepaler van die aanvang van menstruasie. Indien die tydsduur van die luteale fase kunstmatig verleng word, of deur die instandhouding van die luteale funksie of deur die behandeling met progesteron, kan die desiduele veranderinge in die endometriële stroma, soortgelyk aan dié soos gesien in vroeë swangerskap, geïnduseer word.

Die estrogeeninduseerde rypwording van die menslike vaginale epitheel word gewysig soos tydens die toestand van swangerskap, deur die werking van progesteron. Progesteron is belangrik vir die instandhouding van swangerskap aangesien dit menstruasie en uteriene sametrekking onderdruk. Onlangse bevindings het getoon dat, in gekontroleerde kliniese proewe, CYCLOGEST 200 mg nie meer doeltreffend as plasebo in die behandeling van premenstruele sindroom was nie.

INDIKASIE:
CYCLOGEST 200 mg word aangedui vir die aanvulling van ontoereikende afskeiding van progesteron in vroue wat fertilisasieprogramme ondergaan.

KONTRA-INDIKASIES:
Ongediagnoseerde vaginale bloeding.
'n Geskiedenis van trombo-embolitiese afwykings.

WAARSKUWINGS EN VOORSORGMATREËLS:
Progesteron word in die lewer gemetaboliseer en behoort met versigtigheid gebruik te word by pasiënte met hepatiese disfunksie. CYCLOGEST 200 mg bevat die hormoon progesteron wat in beduidende hoeveelhede by vroue teenwoordig is gedurende die tweede helfte van die menstruele siklus en tydens swangerskap. Dit behoort in gedagte gehou te word wanneer pasiënte wat hormoonsensitief is, behandel word. Tensy progestogene deel van die behandeling van borskarsinoom uitmaak, moet dit nie aan sodanige pasiënte toegedien word nie.

GEBRUIK TYDENS SWANGERSKAP EN LAKTASIE:
Progesteron is 'n natuurlike hormoon en behoort nie ongunstige reaksies te ontlok nie, maar geen bewys hiervoor is beskikbaar nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Die dosis van CYCLOGEST 200 mg is 200 mg daagliks per vagina toegedien, maar dit kan verhoog word tot 400 mg tweemaal per dag.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:
Progesterone moet met versigtigheid gebruik word by pasiënte met kardiovaskulêre- of 50943832

nierontoereikendheid, diabetes mellitus, asma, epilepsie, migraine of ander toestande wat vererger kan word deur vogretensie. Dit behoort met omsigtigheid by persone met 'n geskiedenis van geestesdepressie gebruik te word. Menstruasie kan vroeër as wat verwag word voorkom of, meer selde, kan menstruasie vertraag word.

Uitlekking van die basis van die setpil kan voorkom. Nieuwe-effekte van progesteron kan gastrointestinale verstourings, aknee, vogretensie of edeem, gewigstoename, allergiese velreaksies of urtikaria, geestesdepressie, borsveranderinge wat ongerief insluit of minder dikwels, ginekomasie en veranderinge in libido, insluit. Veranderinge in lewerfunksietoets is aangemeld en geelsgug is minder dikwels aangemeld.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Oordosering kan euforie of dismenorree tot gevolg hê. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
Naaswit setpille.

AANBIEDING:
Kartonhouers wat elk 15 setpille bevat, in stulpverpakkingstroke van vyf.

BERGINGSINSTRUKSIES:
Bewaar by of benede 25 °C in 'n droë plek.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIE-NOMMER: Z/21.8.2/294

NAAM EN ADRES VAN DIE REGISTRASIEHOUER:
Actavis Pharma (Pty) Ltd
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DATUM VAN PUBLIKASIE:
Datum van registrasie: 22 Februarie 1994
Hersiëne: 02 Maart 2015

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