SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Hyan FC (Levonorgestrel) Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Film coated tablet contains:

Levonorgestrel Ph. Eur. ..... 0.03 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Oral contraception.

4.2 Posology and method of administration

First treatment cycle

One tablet daily, starting on the first day of the menstrual cycle, at a time of day chosen by the patient. All subsequent tablets must be taken at this time. The contraceptive effect is likely to be reduced if a tablet is delayed by more than three hours. Additional contraceptive precautions are not necessary when initiating treatment.

Subsequent cycles

The tablets are taken daily and pack follows pack without interruption, and without regard to bleeding.

Changing from a combined oral contraceptive (COC)

The first tablet of Hyan FC should be taken on the first day after the last active tablet of the COC pack. In the case of every day (ED) tablet use, the inactive ones should be omitted. Additional contraceptive precautions are not required.

Changing from another Progestogen-only pill (POP)

The switch can be made at any time without interruption of contraceptive protection.

Changing from a progestogen-only parenteral method (implant, injection)

The switch should be made before or when the next injection or implant is due.

Post-partum use

Hyan FC can be initiated up to 21 days post-partum; no additional contraceptive is required. If started after 21 days, additional barrier contraceptive methods should be used for 7 days. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of Hyan FC use or the woman has to wait for her first menstrual period. For additional information on breast feeding women see section Pregnancy and lactation.

Post-abortion or miscarriage use

After a first trimester abortion, Hyan FC may be started at the time of the abortion or miscarriage. Additional contraceptive precautions will not then be required. If started after this time, additional barrier contraceptive precautions are required for 7 days.

Special circumstances requiring additional contraception

Management of missed pills

If the user forgets a pill she should take it as soon as she remembers and carry on with the next pill at the same time. If the pill was more than 3 hours overdue (>27 hours since the last pill was taken) she will not be protected from pregnancy. She should continue normal pill taking but must also use barrier contraceptive methods for the next 7 days. If intercourse took place in the preceding 7 days, the possibility of a pregnancy should be considered. The more tablets are missed, the higher the risk of a pregnancy.

Gastro-intestinal upsets

If vomiting occurs within 2 hours of taking a tablet, another pill should be taken as soon as possible. If a replacement pill is not taken within 3 hours of the scheduled time, additional barrier contraceptive methods should be used for 7 days. In cases of persistent vomiting and/or very severe diarrhoea, additional barrier contraceptive methods should be used during the illness and for 7 days after recovery.

4.3 Contraindications

Hyan FC should not be used in the presence of any of the conditions listed below. Should any of the conditions appear during the use of Hyan FC, the use of the preparation must be discontinued immediately.

- Known or suspected pregnancy.
- Presence or history of severe hepatic disease as long as liver function values have not returned to normal.
- History of or existing thromboembolic processes (e.g. stroke, myocardial infarction).
- Presence or history of liver tumours (benign or malignant).
- Known or suspected sex-steroid influenced malignancies (e.g. current or history of breast cancer).
- Undiagnosed abnormal vaginal bleeding.
- Severe diabetes with vascular changes.
- Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Medical Examination

Assessment of woman prior to starting oral contraceptives and at regular intervals thereafter should include a personal and family medical history of each woman. Physical examination should be guided by this and by the contraindications and warnings for this product. The frequency and nature of these assessments should be based upon relevant guidelines and should be adapted to the individual woman, but should include measurement of blood pressure and, if judged appropriate by the clinician, breast, abdominal and pelvic examination including cervical cytology. Exclude the likelihood of pregnancy before starting treatment.

Warnings

Women should be advised that oral contraceptives do not protect against HIV infections (AIDS) and other sexually transmitted diseases.

Reasons for stopping Hyan FC immediately

When stopping oral contraception, non-hormonal contraception should be used to ensure contraceptive protection is maintained.

1. Occurrence for the first time, or exacerbation, of migrainous headaches or unusually frequent or unusually severe headaches.

2. Sudden disturbances of vision or hearing or other perceptual disorders.

3. First signs of thrombophlebitis or thromboembolic symptoms, for example, unusual pains in or swelling of the legs, stabbing pains on breathing or coughing for no apparent reason, feeling of pain and tightness in the chest.

4. Six weeks before an elective major operation (e.g. abdominal, orthopaedic, any surgery to the legs), medical treatment for varicose veins or prolonged immobilisation (e.g. after accidents or surgery). Do not restart until 2 weeks after full ambulation. In case of emergency surgery, thrombotic prophylaxis is usually indicated (e.g. subcutaneous heparin).

5. Onset of jaundice, hepatitis, itching of the whole body.

6. Clear exacerbation of conditions known to be capable of deteriorating during oral contraception or pregnancy (e.g. recurrence of cholestatic jaundice and/or pruritus which occurred first during pregnancy or previous use of sex steroids).

7. Pregnancy is a reason for stopping immediately because it has been suggested by some investigations that oral contraceptives taken in early pregnancy may slightly increase the risk of foetal malformations. Other investigations have failed to support these findings. The possibility therefore cannot be excluded, but it is certain that if a risk exists at all it is very small.

Circulatory Disorders

In the few epidemiological studies conducted, which are limited in the number of subjects, there is little evidence for an association between progestogen only pills and an increased risk of myocardial infarction and cerebral thromboembolism. The risk of cardiovascular and cerebral events is rather related to increasing age, hypertension, and smoking. In women with hypertension the risk of stroke may be slightly enhanced by progestogen-only pills. There may be a slightly, but not statistically significant, increased risk of venous thromboembolism (deep venous thrombosis, pulmonary embolism) associated with the use of progestogen-only pills. Generally recognized risk factors for venous thromboembolism (VTE) include a positive personal or family history (VTE in a sibling or a parent at a relatively early age), age, obesity and prolonged immobilisation, major surgery or major trauma.

Tumours – Breast Cancer

A meta-analysis from 54 epidemiological studies reported that there is a slightly increased relative risk of having breast cancer diagnosed in women who are currently using oral contraceptives (OC). The observed pattern of increased risk may be due to an earlier diagnosis of breast cancer in OC users, the biological effects of OCs or a combination of both. The additional breast cancers diagnosed in current users of OCs or in women who have used OCs in the last 10 years are more likely to be localised to the breast than those in women who never used OCs. Breast cancer is rare among women under 40 years of age whether or not they take OCs.

The most important risk factor for breast cancer in POP users is the age women discontinues the POP; the older the age at stopping, the more breast cancers are diagnosed. Duration of use is less important and the excess risk gradually disappears during the course of the 10 years after stopping POP use, such that by 10 years there appears to be no excess.

Liver Cancer

In rare cases benign, and in even rarer cases, malignant liver tumours leading in isolated cases to life-threatening intra-abdominal haemorrhage have been observed after the use of hormonal substances such as the one contained in Hyan FC. If severe upper abdominal complaints, liver enlargement or signs of intra-abdominal haemorrhage occur, a liver tumour should be included in the differential diagnostic conditions.

Other conditions – Diabetes

Diabetes mellitus or tendency towards diabetes mellitus requires careful medical supervision.

Ectopic Pregnancy

If there is a history of ectopic pregnancy or one Fallopian tube is missing, the use of Hyan FC should be decided on only after carefully weighing the benefits against the risks. Otherwise, if lower abdominal complaints occur together with an irregular cycle pattern, above all amenorrhoea followed by persistent irregular bleeding, an extrauterine pregnancy must be considered.

Persistent ovarian follicles

Persistent ovarian follicles (often referred to as functional ovarian cysts) may occur during the use of Hyan FC. Most of these follicles are asymptomatic, although some may be accompanied by pelvic pain or dyspareunia. In most

cases, the enlarged follicles disappear spontaneously during two to three months of observation.

Chloasma

Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking Hyan FC.

Lactose intolerance

Each tablet of this medicinal product contains 85.82 mg lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, fructose intolerance or glucose-galactose malabsorption should not take this medicine.

Bleeding patterns – Menstrual changes

A usual feature of all progestogen-only oral contraceptives is that they can produce an initial irregularity of the bleeding pattern, but such irregularity tends to decrease with time. Some women may experience amenorrhoea. For those reasons the possibility of such changes in menstrual rhythm should, as a precaution, be pointed out to the patient before the start of tablet-taking.

Amenorrhoea / Missed menstruation

If no menstrual bleeding has occurred within 6 weeks after the last menstrual bleeding, pregnancy must be excluded before tablet-taking is continued. If pregnancy has been excluded and the amenorrhoea lasts longer than 3 months or recurs repeatedly, Hyan FC should be withheld until normal menstrual bleeding has been restored.

Procedure in the event of irregular bleeding

Irregular bleeding is not a medical reason for stopping tablet-taking, as long as organic causes for such bleeding and pregnancy can be ruled out, provided it is ensured that the patient is fully compliant. It is extremely inadvisable to attempt to influence cycle disturbances by the additional administration of an oestrogen. This would only serve to reverse the changes brought about by Hyan FC in the cervical mucus, thereby seriously reducing the contraceptive effect.

4.5 Interaction with other medicinal products and other forms of interaction

Drug interactions which result in an increased clearance of sex hormones can lead to breakthrough bleeding and oral contraceptive failure. This has been established with many hepatic enzyme-inducing drugs including barbiturates, primidone, phenytoin, carbamazepine, rifampicin, oxcarbazepine, St. John's wort (Hypericum perforatum), griseofulvin, rifabutin, aprepitant, bosentan, nevirapine, rufinamide and topiramate.

For women receiving long-term therapy with hepatic enzyme inducers, another method of contraception should be used. Women receiving short courses of enzyme inducers should take additional non-hormonal (except rhythm or temperature methods) contraceptive precautions during the time of concurrent medication and for 28 days afterwards.

Progestogens may interfere with the metabolism of other drugs. Accordingly, plasma and tissue concentrations may be increased (e.g. cyclosporin) or decreased (e.g. lamotrigine). Progestogens may either enhance or reduce the anticoagulant effects of coumarins and may antagonise the anticoagulant effects of phenindione.

Note: The prescribing information on concomitant medications should be consulted to identify potential interactions.

Effect on blood chemistry

The use of oral contraceptives may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, plasma levels of carrier proteins and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis. Laboratory staff should therefore be informed about oral contraceptive use when laboratory tests are requested.

4.6 Fertility, pregnancy and lactation

Pregnancy

The administration of Hyan FC during pregnancy is contraindicated. If pregnancy occurs during medication with Hyan FC, the preparation is to be withdrawn immediately. Epidemiological studies have revealed neither an increased risk of birth defects in children born to women who used oral contraceptives prior to pregnancy, nor a teratogenic effect when oral contraceptives were taken inadvertently during early pregnancy.

Lactation

Hormonal contraceptives are not recommended as the contraceptive method of first choice during lactation, but progestogen-only methods are considered to comprise the next choice category after non-hormonal methods. Progestogen-only pills, like Hyan FC, can be used by breast feeding women as there appears to be no evidence to suggest that progestogen-only pills have a detrimental effect on breast milk or infant growth or development. A breast-feeding woman can start a progestogen-only treatment, like Hyan FC, up to 21 days post-partum without the need for additional contraceptive protection. When starting later, the woman should be advised to additionally use a barrier method for the first 7 days of tablet taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of Hyan FC use or the woman has to wait for her first menstrual period.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The undesirable effects are mapped to the respective System Organ Class (SOC):

- Immune system disorders: Allergic reaction
- Metabolism and nutrition disorders: Increased or decreased weight
- Psychiatric disorders: Depressed mood
- Nervous system disorders: Migraine, Headache, Dizziness
- Gastrointestinal disorders: Vomiting, Nausea
- Reproductive system and breast disorders: Changes in vaginal bleeding pattern including irregular bleeding, amenorrhoea; Decreased or increased libido

The following serious adverse events have been reported in women using OCs, which are discussed in section Special warnings and precautions for use:

- Venous thromboembolic disorders
- Arterial thromboembolic disorders
- Strokes (e.g. transient ischaemic attack, ischaemic stroke, haemorrhagic stroke)
- Benign and malignant liver tumours leading in isolated cases to life-threatening intra-abdominal haemorrhage
- Diabetes mellitus or tendency towards diabetes mellitus requiring careful medical supervision

- A history of ectopic pregnancy or a missing Fallopian tube requiring careful weighing of the benefits of Hyan FC against the risks

The frequency of breast cancer is very slightly increased among OC users. As breast cancer is rare in women under 40 years of age, the excess number is small in relation to the overall risk of breast cancer. For progestogen-only pills (POPs) the evidence for causation is less conclusive than that for combined oral contraceptives (COCs).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS): https://pv.pharmacyboardkenya.org

4.9 Overdose

There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in this case are nausea, vomiting and slight vaginal bleeding. There are no antidotes and further treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The contraceptive action of Hyan FC may be explained as follows: it changes the cervical mucus so that a barrier is formed against the migration of sperm into the uterine cavity; ovulation is impeded because of changes in the structure of the endometrium. As a rule there is no inhibition of ovulation. Evidence suggests that a reduction in corpus luteum function may also contribute to the contraceptive action.

5.2 Pharmacokinetic properties

As is known from a series of studies comprising various preparations and dosages, levonorgestrel is rapidly and completely absorbed after oral administration. Following ingestion of Hyan FC, maximum serum levels of about 0.8 ng/ml were determined at 1 hour. Thereafter, drug serum levels declined biphasically with half-lives of 0.2 - 0.4 hours and 20 hours. Metabolic clearance rate from serum or plasma accounts for 1.0 to 1.5 ml/min/kg.

Levonorgestrel is not excreted in unchanged form but as metabolites, which are eliminated with a half-life of about 1 day. Almost equal dose parts are excreted via the kidney and the liver. The biotransformation follows the known pathways of steroid metabolism. No pharmacologically active metabolite is known.

Levonorgestrel is bound to serum albumin and to SHBG. Only about 1.5% of the respective total serum drug levels are present as free steroid, but about 65% are specifically bound to SHBG. The relative portions (free, albumin-bound, SHBG-bound) depend on the SHBG serum concentrations. Following induction of the carrier protein, the SHBG-bound portion increases while the unbound and albumin-bound portions decrease.

Following daily repeated administration, levonorgestrel accumulates by a factor of approx. 2. Steady-state conditions are reached after about 3-4 days. Levonorgestrel pharmacokinetics is influenced by SHBG serum levels. Under Hyan FC treatment, a slight decline of the SHBG serum levels could occur. The daily ingestion of 0.15 mg levonorgestrel (corresponding to the 5-fold daily dose of Hyan FC) led to a 50% decrease in the SHBG serum levels and to a 40% reduction in levonorgestrel through-levels after 2-3 weeks. A similarly directed effect of Hyan FC should account, however, for a decrease of only about 10% in the two parameters.

The absolute bioavailability of levonorgestrel from Hyan FC was determined to be 82% of the dose. About 0.1% of the maternal dose can be transferred to a newborn via milk.

5.3 Preclinical safety data

Non-clinical data reveal no special risk for humans based on studies of repeated dose toxicity, genotoxicity, carcinogenicity and toxicity to reproduction which is not already included in other relevant sections. However, it should be kept in mind that sexual steroids might stimulate the growth of hormone-dependent tissues and tumors.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Lactose monohydrate
- Polyvinyl pyrrolidone K-25
- Colloidal silicon dioxide
- Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30°C.

Keep out of reach and sight of children.

6.5 Nature and contents of container

Blister pack of 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

SAI PHARMACEUTICALS LTD

8. MARKETING AUTHORISATION NUMBER(S)

H2005/383/16732/R1.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29-06-2026

10. DATE OF REVISION OF THE TEXT

22-08-2026