

Dienogest (Dienogest Spirig HC 2 mg tablets) Notification to Healthcare Professionals Regarding Packaging and Leaflet Deficiency

Date: 09/24/2025

Dear Healthcare Professionals,
Greetings,

With reference to the report received from one of the healthcare institutions regarding a packaging defect in Dienogest Spirig HC 2 mg tablets (Batch No. LF39532F), we would like to inform you of the following after reviewing the batch release data:

This information is being communicated in agreement with the Saudi Food and Drug Authority (SFDA).

Nature of the Issue:

It has been found that the outer packaging and patient information leaflet of the affected batch are written in a foreign language other than English or Arabic, and no versions in Arabic or English were provided. This is non-compliant with SFDA requirements for ensuring clarity of information for users.

Actions Taken:

- Coordination is ongoing with NUPCO to implement the necessary corrective actions.
- The patient information leaflet has been printed in English.

Recommendations:

- All healthcare professionals are kindly requested to refer to the English version of the Patient Information Leaflet for this batch to ensure that all necessary information is clearly communicated for safe and effective use.
- If you require more details regarding this batch, please contact the company at 0562442566 or via email at Regulatory@aodci.com.sa.
- If you notice any packaging with unclear information for any other batch, please report it immediately to the SFDA reporting system: <https://ade.sfda.gov.sa/Home/Report>.

Attachments:

- Please refer to the Patient Information Leaflet provided in Annex 1.

Call for Reporting

If you experience any adverse events or have concerns related to *Dienogest Spirig HC 2 mg tablets* please report via:

- **Marketing Authorisation Holder (MAH):**
Spirig HealthCare AG
Industriestrasse 29, 4622 Egerkingen, Switzerland
Tel: +41 62 388 85 00 • Email (PV): pharmacovigilance@spirig-healthcare.ch
- **National Pharmacovigilance Center (NPC) – Saudi Food & Drug Authority (SFDA):**
Call Center: 19999
Email: npc.drug@sfda.gov.sa
Website: <https://ade.sfda.gov.sa>

We appreciate your commitment to patient safety and quality care, and we thank you for your continued cooperation.

Sincerely,
Arabian Oasis for Development and Commercial Investment Company



ANNEX 1 Package leaflet: information for the user DIENOGEST SPIRIG HC 2 mg tablets

Dienogest

Information for patients

Read this leaflet carefully before taking or using this medicine. This medicine has been prescribed to you personally and you must not give it to anyone else. Even if they have the same symptoms of illness as you, the medicine could harm them.

Keep the leaflet, you may want to read it again later.

Dienogest Spirig HC®

Spirig HealthCare AG

What is Dienogest Spirig HC and when is it used?

Dienogest Spirig HC is a hormone preparation for the treatment of endometriosis. Endometriosis is when the lining of the uterus also grows outside the uterine cavity, which can lead to symptoms such as lower abdominal pain and painful menstrual bleeding. The dienogest contained in Dienogest Spirig HC, when taken daily, reduces the endometrium tissue and reduces the lower abdominal pain associated with endometriosis.

On prescription from the doctor.

What should be considered?

Dienogest Spirig HC is NOT a contraceptive. If you do not want to get pregnant while taking Dienogest Spirig HC, you should use condoms or other non- hormonal contraceptives. You must not take or use hormonal contraceptives of any kind (tablets, patches, intrauterine systems) while using Dienogest Spirig HC.

When should Dienogest Spirig HC not be taken/used?

Your doctor or Your doctor will decide if you have any medical reasons for not taking Dienogest Spirig HC. Do not take Dienogest Spirig HC:

- if you have a blood clot (thromboembolic disease) in the veins. These can occur, for example, in the blood vessels of the legs (e.g. deep vein thrombosis) or the lungs (pulmonary embolism). See also, under «When should caution be exercised when taking Dienogest Spirig HC?» -
- «Influence on blood clotting, risk of venous vascular disease»,
- if you have or have had a serious disease of the arteries, including cardiovascular disease, such as heart attack, stroke or heart disease, which

leads to a reduced blood supply (angina pectoris). See also under, «When should caution be exercised when taking Dienogest Spirig HC?» -

- «Influencing blood clotting, risk of venous vascular disease»,
- if you suffer from diabetes mellitus and your blood vessels are already damaged as a result,
- if you have or have had severe liver disease (and the liver values in the blood have not yet returned to normal). Symptoms of liver disease can be, for example, yellowing of the skin or itching of the whole body,
- if you have or have had a liver tumor (benign or malignant),
- in the case of existing or previous cancers (e.g. of the breast or uterine lining) that are influenced by sex hormones,
- in the case of vaginal bleeding, the cause of which has not been clarified,
- if you are hypersensitive (allergic) to Dienogest or any of the excipients of Dienogest Spirig HC.

If any of the above conditions or circumstances occur for the first time while taking Dienogest Spirig HC, you must stop taking Dienogest Spirig HC and contact your doctor or doctor. Inform your doctor.

When should caution be exercised when taking Dienogest Spirig HC?

In some situations, special caution is required when taking Dienogest Spirig HC and regular check-ups with a doctor may be necessary. If any of the following apply to you, you will need to consult your doctor or doctor. Inform your doctor.

If:

- you have or have had a blood clot (venous thromboembolism) or close family members have had a blood clot at an early age,
- breast cancer has occurred in a close relative,
- you suffer from depression,
- you have high blood pressure or develop high blood pressure on Dienogest Spirig HC,
- you develop liver disease while taking Dienogest Spirig HC. Symptoms of liver disease can be, for example, yellowing of the skin or eyes or itching of the whole body. Tell your doctor or Your doctor, if these symptoms have occurred in a previous pregnancy,
- you suffer from diabetes mellitus or were diabetic during a past pregnancy,
- You have or have had chloasma (yellowish-brown pigment spots, mainly on the

face). In this case, it is recommended to avoid direct sunlight or ultraviolet light,

- you suffer from lower abdominal pain while taking Dienogest Spirig HC, this could be an indication of enlarged ovarian follicles,
- you have been diagnosed with an increased risk of bone loss (osteoporosis).

If you become pregnant while taking Dienogest Spirig HC, you have a slightly increased risk of an extrauterine pregnancy (the embryo develops outside the uterus). Tell your doctor or Tell your doctor before you start taking Dienogest Spirig HC if you have had an extrauterine pregnancy in the past, or if the function of your fallopian tubes is impaired.

Influence on blood clotting, risk of venous vascular disease

Some studies show a slight increase in the risk of a blood clot in the veins (venous thromboembolism) when taking progestin monopreparations (mini-pill). Shortly after delivery, the risk of a blood clot forming may also be increased. Very rarely, blood clots can leave permanent disabilities or even lead to death.

The risk of vascular occlusion in the veins increases:

- with increasing age,
- if you are overweight,
- if you or a close family member had a blood clot in your leg (thrombosis), lungs (pulmonary embolism) or another organ at an early age,
- if you have to undergo surgery, if you have had a serious accident or if you have to stay on strict bed rest for some time. It is important to consult your doctor or Inform your doctor that you are taking Dienogest Spirig HC before any planned surgery or in the event of any event mentioned above, as you will need to stop taking Dienogest Spirig HC. Your doctor or Your doctor will tell you when you can start taking Dienogest Spirig HC again, usually about 2 weeks after you can walk again.

Influence on blood clotting, risk of arterial vascular disease

The use of progestin monopreparations (mini-pill) is also associated with an increased risk of heart attacks or strokes. In women with high blood pressure, the risk of stroke could increase slightly by taking the progestin monopreparations (mini-pill).

The risk of vascular occlusion in the arteries increases:

- if you smoke. You are strongly advised to stop smoking if you are taking Dienogest Spirig HC, especially if you are over 35 years of age.

- if you are overweight,
- if a close family member has had a heart attack or stroke at an early age,
- if you have high blood pressure.

Stop taking Dienogest Spirig HC immediately and seek medical attention immediately. Your doctor will alert you if you notice any possible signs of a blood clot on you, such as:

- severe pain and/or swelling in one leg,
- sudden severe chest pain, possibly radiating to the left arm,
- sudden shortness of breath,
- sudden cough without a clear cause,
- unusual, severe, or persistent headache or worsening of a migraine,
- partial or complete loss of vision or double vision,
- slurred speech or problems speaking,
- dizziness or fainting,
- Weakness, strange feeling or numbness in one part of the body.

Cancer

Whether or not Dienogest Spirig HC increases the risk of breast cancer is not clear from the data currently available. Breast cancer is detected slightly more often in women who take hormones than in women who do not take hormones. But it is not known if this is caused by the treatment. The incidence of breast tumors slowly decreases after discontinuation of hormone treatments. It is important that you examine your breasts regularly. If you feel lumps, you need to consult your doctor or doctor. See your doctor.

In rare cases, benign liver tumors and, even more rarely, malignant liver tumors have been detected in users of hormones. Find your doctor or Your doctor if you have unusually severe abdominal pain.

Psychiatric disorders

Some women who take sex hormones, such as those found in Dienogest Spirit HC, report depression or depression. Depression can be severe and occasionally lead to suicidal thoughts. If you experience mood swings and depressive symptoms, seek medical advice from a doctor as soon as possible.

Changes in bleeding pattern

In most patients, changes in the menstrual bleeding pattern occur during treatment with Dienogest Spirig HC. (see also

«What side effects can Dienogest Spirig HC have?»).

Uterine bleeding, for example in women with so-called adenomyosis (a form of endometriosis in which the foci grow in the wall of the uterus) or a so-called uterine leiomyoma (benign tumor of the smooth uterine muscles), can be intensified by taking Dienogest Spirig HC. Heavy and prolonged bleeding can lead to anemia, which can be severe in some cases.

Change in bone mineral density

Long-term use of Dienogest Spirig HC may lead to a reduction in bone mineral density (BMD). This was shown in a study in adolescents aged 12 to 18 years, but may be important for patients of all ages. For this reason, your doctor will weigh the benefits of using Dienogest Spirig HC. This is especially true if you are under 25 years of age and taking into account other risk factors, especially those that promote bone loss (osteoporosis). These risk factors include:

- if you suffer from metabolic bone disease (MBD);
- if someone in your immediate family suffers from osteoporosis;
- if you have ever had a broken bone that was not caused by a fall or accident;
- if you are using other medicines, such as epilepsy medications or steroids, which may cause bone loss;
- if you have a low body mass index or suffer from eating disorders such as anorexia or bulimia;
- if you drink alcohol regularly,
- if you smoke.

If you take Dienogest Spirig HC, you must follow a healthy diet that includes regular calcium (e.g. through dairy products) and vitamin D intake (e.g. through fatty fish such as salmon). Regular exercise using weights can also have a positive effect on your bone mineral density.

Dienogest Spirig HC contains lactose.

Therefore, please do not take Dienogest Spirig HC until you have consulted your doctor or health care professional if you know that you suffer from a sugar intolerance.

Interactions with other medicines

The effects of Dienogest Spirig HC may be affected by medicines used to treat:

- epilepsy (such as phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate and felbamate),
- tuberculosis (e.g. rifabutin, rifampicin),

- HIV and hepatitis C infections (protease inhibitors and non-nucleoside reverse transcriptase inhibitors),
- of high blood pressure in the lungs (bosentan),
- of a special type of excessive drowsiness (Modafinil),
- or by taking herbal supplements containing St. John's wort.

The level of Dienogest Spirig HC in your blood is increased by medicines such as:

- Medicines for fungal infections (e.g. itraconazole, voriconazole, fluconazole),
- Antibiotika (z.B. Erythromycin, Clarithromycin),
- cardiovascular medications (e.g. diltiazem, verapamil),
- or grapefruit juice.

Consult your doctor or pharmacist before taking any medicines. Ask your doctor or pharmacist for advice.

Influencing laboratory values

The use of Dienogest Spirig HC may affect the results of certain laboratory tests. If you want to have a blood test, tell your doctor or Your doctor or laboratory staff will tell you that you are taking Dienogest Spirig HC.

Driving ability and operating machines

The influence of Dienogest Spirig HC on the ability to drive and operate machines has not been investigated. Tell your doctor, pharmacist or pharmacist. Your doctor, pharmacist, if you

- suffer from other diseases,
- have allergies or
- take other medicines (even those you bought yourself!) or use them externally!

Can Dienogest Spirig HC be taken during pregnancy or breastfeeding?

If you are pregnant or breastfeeding, do not take Dienogest Spirig HC.

How do you use Dienogest Spirig HC?

Always take Dienogest Spirig HC exactly as directed by your doctor. Please ask your doctor or pharmacist if you are not quite sure. Unless otherwise prescribed by a doctor, the following information applies to Dienogest Spirig HC.

Take 1 tablet daily, along with some liquid. Dienogest Spirig HC can be taken with or without concomitant food intake.

When you have taken all the tablets from one pack, start taking them from the next

pack without interruption. Also, continue taking the tablets on the days of your menstrual period.

The tablets can be started on any day of your cycle.

If you take more Dienogest Spirig HC than you should:

There are no reports of harmful effects after taking too many Dienogest Spirig HC tablets. However, disturbances in the bleeding pattern are to be expected. If you are worried, seek advice from your doctor.

If you forget to take Dienogest Spirig HC or suffer from vomiting or diarrhea:

Dienogest Spirig HC is less effective if you forget to take a tablet. If you forget one or more tablets, take one tablet as soon as you notice it. Other forgotten tablets should not be taken at the same time. The next day, take the following tablet again at the usual time.

If you vomit in the first 3 to 4 hours after taking Dienogest Spirig HC, or if you experience severe diarrhea, the active ingredients in the tablet may not have been fully absorbed into your body. This situation is similar to forgetting a tablet. After vomiting or diarrhea, you need to take another tablet as soon as possible.

Children and adolescents

Dienogest Spirig HC will not be used in children before menarche (first menstruation).

Long-term use of Dienogest Spirig HC may lead to a reduction in bone mineral density (BMD) (see "When to use caution when taking Dienogest Spirig HC?"). In adolescents (especially <16 years of age), your doctor will carefully weigh this risk against the benefits of using Dienogest Spirig HC.

Stick to the dosage indicated in the package leaflet or prescribed by your doctor. If you think the medicine is too weak or too strong, talk to your doctor or pharmacist.

What side effects can Dienogest Spirig HC have?

Talk to your doctor or health care professional about any adverse events, especially serious or long-lasting medical conditions, or any changes in your medical condition that you suspect are caused by Dienogest Spirig HC.

Like all medicines, Dienogest Spirig HC can cause side effects, although not everyone gets them. Side effects are more common during the first month of treatment with Dienogest Spirig HC and decrease with continued use. You may notice an altered bleeding pattern, such as spotting, irregular bleeding, and absence of bleeding.

Common (affects 1 to 10 in 100 users)

The most common side effects are headache, chest discomfort, depressive mood and acne. Furthermore, the following are common:

Weight gain, sleep disorders, nervousness, loss of interest in sex or mood changes, attention disorder, migraine, nausea, abdominal pain, flatulence, vomiting, hair loss, back pain, ovarian cysts, vaginal bleeding including spotting, hot flashes, weak condition, irritability.

Uncommon (affects 1 to 10 out of 1000 users)

Anemia, weight loss, increased appetite, anxiety, depression, imbalance of the autonomic nervous system (controls the unconscious bodily functions, such as sweating), dry eyes, tinnitus, non-specific circulatory disorders, palpitations, low blood pressure, shortness of breath, diarrhea, constipation, gastrointestinal inflammation, gingivitis, dry skin, extreme sweating, severe itching of the whole body, increased male hair, brittle nails, Dermatitis, hair growth disorders, hypersensitivity to light, skin pigmentation disorders, bone pain, muscle spasms, pain or heaviness in the arms, hands, legs or feet, urinary tract infections, vaginal fungal infection, vaginal discharge, lower abdominal pain, inflammation and dehydration of the external genitalia including the vagina (atrophic vulvovaginitis) lumps in the breast, water retention.

Please inform your doctor or pharmacist or Your doctor or pharmacist if any of the listed side effects affect you significantly.

If you notice any side effects, contact your doctor or pharmacist. Your doctor or pharmacist. This applies in particular to side effects not specified in this leaflet.

What else should be considered?

The medicine must only be used up to the date marked "EXP" on the container.

Storage Note

Do not store above 30°C.

Store in the original packaging away from light. Keep out of reach of children.

Further information

For further information, please contact your doctor or pharmacist or Your doctor or pharmacist. These persons have the detailed specialist information.

What is in Dienogest Spirig HC?

Active substances

The active ingredient is Dienogest. Each tablet contains 2 mg Dienogest

Auxiliary supplies

Lactose-Monohydrat, Maisstärke, Povidone K-30, Magnesiumstearat

Licence number

67511 (Swissmedic).

Where can you get Dienogest Spirig HC? What packs are available?

Dienogest Spirig HC is only available in pharmacies with a doctor's prescription. There are packs of 28 and 84 tablets.

Marketing authorisation holder

Spirig HealthCare AG, Egerkingen.

This package leaflet was last reviewed by the Medicines Agency (Swissmedic) in July 2020.