

Taytulla® is indicated for pregnancy prevention^{1,†}

THE FUTURE OF ORAL CONTRACEPTIVES HAS **GELLED**

Taytulla is the first and only oral contraceptive
softgel capsule



Swallow whole.

Pregnancy prevention
with short, light periods^{1,2,*}

*Some women taking Taytulla had a period lasting less than 3 days on average at the end of the study.²

†If you are moderately obese, discuss with your healthcare provider whether Taytulla is appropriate for you.¹

IMPORTANT RISK INFORMATION

WARNING TO WOMEN WHO SMOKE

Do not use Taytulla if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from birth control pills, including death from heart attack, blood clots, or stroke. This risk increases with age and the number of cigarettes you smoke.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.

Taytulla®

(norethindrone acetate and
ethinyl estradiol capsules and
ferrous fumarate capsules)

1 mg/20 mcg

Is Taytulla® right for you?

Taytulla is a prescription birth control pill used for the prevention of pregnancy. If you are moderately obese, discuss with your healthcare provider whether Taytulla is appropriate for you.¹

In a study, women taking Taytulla had short, light periods.² Plus, some women taking Taytulla found their periods to be lighter than normal.² Women from a study who did not take oral contraceptives experienced longer periods.³

Most women taking Taytulla had a period that lasted less than 3 days on average at the end of the 6-month study.²

What is Taytulla?



Swallow whole.

Taytulla provides birth control in a softgel capsule. Each opaque, pale pink capsule contains a combination of 2 female hormones. The hormones are an estrogen called ethinyl estradiol and a progestin called norethindrone acetate.¹

Birth control pills do not protect you against sexually transmitted disease, including HIV, the virus that causes AIDS.¹

How many capsules contain hormones?

Taytulla has 24 days of "active" capsules that contain hormones and 4 days of "reminder" capsules that do not contain hormones.¹ Taytulla is an example of an extended-regimen oral contraceptive.



IMPORTANT RISK INFORMATION (continued)

Who should not take Taytulla?

Do not use Taytulla if you have or have had blood clots, history of heart attack or stroke, high blood pressure that medicine cannot control, breast cancer or any cancer that is sensitive to female hormones, liver disease or liver tumors, unexplained bleeding from the vagina, if you are or may be pregnant, or if you take Hepatitis C drugs containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, as this may increase levels of liver enzymes in the blood.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.

What about bleeding and spotting between my periods?

Irregular vaginal bleeding or spotting may occur while you are taking Taytulla. Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding, which is a flow much like a regular period. Irregular bleeding occurs most often during the first few months of oral contraceptive use, but may also occur after you have been taking the capsule for some time. Such bleeding may be temporary and usually does not indicate any serious problems. It is important to continue taking your capsules on schedule. If the bleeding occurs in more than one cycle, is unusually heavy, or lasts for more than a few days, call your healthcare provider.¹

What if I miss my scheduled period?



It is not uncommon to miss your period. However, if you go 2 or more months in a row without a period, or you miss your period after a month where you did not take all of your capsules correctly, call your healthcare provider because you may be pregnant. Stop taking Taytulla if you are pregnant.¹

IMPORTANT RISK INFORMATION (continued)

What else should I know about taking Taytulla?

Treatment with Taytulla should be stopped if you have a blood clot, and at least 4 weeks before and through 2 weeks after major surgery. You should not take Taytulla any earlier than 4 weeks after having a baby, or if you are breastfeeding. If you experience yellowing of the skin or eyes due to problems with your liver, you should stop taking Taytulla. If you are pre-diabetic or diabetic, your doctor should monitor you while using Taytulla. Your doctor should evaluate you if you have any significant change in headaches or irregular menstrual bleeding.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.

Taytulla®

(norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules)

1 mg/20 mcg

How do I take Taytulla®?

First, decide what time of day you want to take your capsule. It's important that you remember to take Taytulla in the order directed on the package at the same time every day. Taytulla can be taken without regard to meals.¹

The Taytulla capsule pack has 24 active pink capsules (with hormones) to be taken for 24 days, followed by 4 reminder maroon capsules (without hormones) to be taken for the next 4 days.

The first and only birth control available in a softgel capsule.¹

Designed with absorption and solubility in mind.⁴

Your Taytulla capsule pack¹

START HERE

FOR BOTH SUNDAY STARTERS AND DAY-1 STARTERS

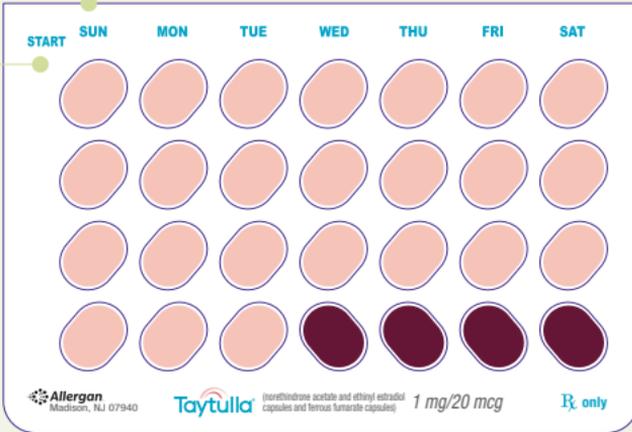
WEEK 1

WEEK 2

WEEK 3

WEEK 4

DAY-1 STARTERS: If your period begins on a day other than Sunday, place the day label strip that starts with the first day of your period.



TAKE PILLS IN THIS DIRECTION FROM LEFT TO RIGHT EACH WEEK

Take 1 Taytulla capsule every day, for 28 days, until the pack is empty. Then start a new capsule pack.¹ The maroon capsules keep you in the habit of taking a capsule every day and help remind you that it's time to start a new pack. Each capsule should be swallowed whole.

If you have more questions about Taytulla, see the enclosed Brief Summary or talk to your healthcare provider.

IMPORTANT RISK INFORMATION (continued)

What are the most serious risks of taking Taytulla?

Taytulla increases the risk of serious conditions including blood clots, stroke, and heart attack. These can be life-threatening or lead to permanent disability.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.



Swallow whole.

Ready for Taytulla?

- In a clinical study, women on Taytulla had short, light periods²
- Some women taking Taytulla had a period that lasted less than 3 days on average²

Talk to your healthcare provider today about Taytulla and find out if it's right for you.



IMPORTANT RISK INFORMATION (continued)

What are the possible side effects of Taytulla?

The most common side effects reported by women taking Taytulla in a study were nausea/vomiting, headache, spotting or bleeding between menstrual periods, painful menstruation, weight change, breast tenderness, acne, abdominal pain, anxiety, and depression.

Birth control pills do not protect you against any sexually transmitted disease, including HIV, the virus that causes AIDS.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.

Taytulla®

(norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules)

1 mg/20 mcg

Taytulla® is indicated for pregnancy prevention^{1,*}

THE FUTURE OF ORAL CONTRACEPTIVES HAS **GELLED**

- Pregnancy prevention in the first and only oral contraceptive softgel capsule¹
- Taytulla may give women short, light periods²
 - Most women taking Taytulla had a period that lasted less than 3 days on average at the end of the 6-month study²
- Talk to your healthcare provider today to see if Taytulla is right for you



*If you are moderately obese, discuss with your healthcare provider whether Taytulla is appropriate for you.

To find out more about Taytulla, visit www.taytulla.com



Taytulla® Savings Program

Eligible patients may save with the Taytulla® Savings Program[†]

Visit allergansavingscard.com/Taytulla to sign up for a Taytulla® Savings Card.

[†]Maximum savings limits apply, patient out-of-pocket expense will vary. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. **Please see Program Terms, Conditions, and Eligibility Criteria at allergansavingscard.com/Taytulla.**

IMPORTANT RISK INFORMATION

WARNING TO WOMEN WHO SMOKE

Do not use Taytulla if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from birth control pills, including death from heart attack, blood clots, or stroke. This risk increases with age and the number of cigarettes you smoke.

Please see Important Risk Information throughout and enclosed Brief Summary, including Boxed Warning.

References: 1. Taytulla (norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules) [prescribing information]. Madison, NJ: Allergan Inc.; 2019. 2. Data on file. Allergan USA, Inc. 3. Creinin MD, Keveline S, Meyn LA. *Contraception*. 2004;70(4):289-292. 4. Aylwin EA, Banbury S, Ferdinando JJC, de Nijs H, inventors; RP Scherer Technologies Inc, assignee. Oral pharmaceutical compositions containing long-chain triglycerides and lipophilic [sic] surfactants. US patent 6,652,880. November 25, 2003.

Taytulla®

(norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules)
1 mg/20 mcg



© 2020 Allergan. All rights reserved. Allergan® and its design are trademarks of Allergan, Inc. Taytulla® and its design are registered trademarks of Allergan Pharmaceuticals International Limited. TAY133257 02/20

Brief Summary of Patient Information Taytulla Capsules

This information does not take the place of talking to your doctor about your medical condition or your treatment.

Taytulla
(norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules)
1 mg/20 mcg

WARNING TO WOMEN WHO SMOKE

Do not use Taytulla if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from birth control pills, including death from heart attack, blood clots or stroke. This risk increases with age and the number of cigarettes you smoke.

Birth control pills help to lower the chances of becoming pregnant when taken as directed. They do not protect against HIV infection (AIDS) and other sexually transmitted infections.

What is Taytulla?

Taytulla is a prescription birth control pill. It contains two female hormones, an estrogen called ethinyl estradiol, and a progestin called norethindrone acetate.

Women with a BMI above 35 kg/m² were not studied in the clinical trial, so it is not known how well Taytulla protects against pregnancy in such women. If you are overweight, discuss with your healthcare provider whether Taytulla is the best choice for you.

Who should not take Taytulla?

Your healthcare provider will not give you Taytulla if you have:

- Ever had blood clots in your arms, legs (deep vein thrombosis), lungs (pulmonary embolism), or eyes (retinal thrombosis)
- Ever had a stroke
- Ever had a heart attack
- Certain heart valve problems or heart rhythm abnormalities that can cause blood clots to form in the heart
- An inherited problem with your blood that makes it clot more than normal
- High blood pressure that medicine cannot control
- Diabetes with kidney, eye, nerve, or blood vessel damage
- Ever had certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision, or have any migraine headaches if you are over age 35
- Ever had breast cancer or any cancer that is sensitive to female hormones
- Liver disease, including liver tumors
- Take any Hepatitis C drug combination containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme "alanine aminotransferase" (ALT) in the blood

Also, do not take birth control pills if you:

- Smoke and are over 35 years old
- Are or suspect you are pregnant
- Have any unexplained bleeding from the vagina

Birth control pills may not be a good choice for you if you have ever had jaundice (yellowing of the skin or eyes) caused by pregnancy, also called cholestasis of pregnancy.

Tell your healthcare provider if you have ever had any of the above conditions (your healthcare provider may recommend another method of birth control).

What else should I know about taking Taytulla?

Birth control pills do **not** protect you against any sexually transmitted infection, including HIV, the virus that causes AIDS.

Do not skip any pills, even if you do not have sex often.

If you miss a period, you could be pregnant. However, some women miss periods or have light periods on birth control pills, even when they are not pregnant. Contact your healthcare provider for advice if you:

- Think you are pregnant
- Miss one period and have not taken your birth control pills every day
- Miss two periods in a row

Birth control pills should not be taken during pregnancy. However, birth control pills taken by accident during pregnancy are not known to cause birth defects.

You should stop Taytulla at least four weeks before you have surgery and not restart it until at least two weeks after the surgery, due to an increased risk of blood clots.

If you are breastfeeding, consider another birth control method until you are ready to stop breastfeeding. Birth control pills that contain estrogen, like Taytulla, may decrease the amount of milk you make. A small amount of the pill's hormones pass into breast milk.

Tell your healthcare provider about all medicines and herbal products that you take. Some medicines and herbal products may make birth control pills less effective, including:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John's wort
- topiramate

Use a back-up or alternative birth control method when you take medicines that may make birth control pills less effective.

Birth control pills may interact with lamotrigine, an anticonvulsant used for epilepsy. This may increase the risk of seizures, so your healthcare provider may need to adjust the dose of lamotrigine.

If you have vomiting or diarrhea, your birth control pills may not work as well. Use another birth control method, like a condom and spermicide, until you check with your healthcare provider.

Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone.

If you are scheduled for any laboratory tests, tell your healthcare provider that you are taking birth control pills. Certain blood tests may be affected by birth control pills.

What are the most serious risks of taking Taytulla?

Like pregnancy, birth control pills increase the risk of serious blood clots, especially in women who have other risk factors, such as smoking, obesity, or age greater than 35. This increased risk is highest when you first start taking birth control pills and when you restart the same or different birth control pills after not using them for a month or more.

It is possible to die from a problem caused by a blood clot, such as a heart attack or a stroke.

Some examples of serious blood clots are blood clots in the:

- Legs (deep vein thrombosis)
- Lungs (pulmonary embolus)
- Eyes (loss of eyesight)
- Heart (heart attack)
- Brain (stroke)

Women who take birth control pills may get:

- High blood pressure
- Gallbladder problems
- Rare cancerous or noncancerous liver tumors

All of these events are uncommon in healthy women.

Call your healthcare provider right away if you have:

- Persistent leg pain
- Sudden shortness of breath
- Sudden blindness, partial or complete
- Severe pain or pressure in your chest
- Sudden, severe headache unlike your usual headaches
- Weakness or numbness in an arm or leg, or trouble speaking
- Yellowing of the skin or eyeballs

What are the common side effects of birth control pills?

The most common side effects of birth control pills are:

- Spotting or bleeding between menstrual periods
- Nausea
- Breast tenderness
- Headache

These side effects are usually mild and usually disappear with time.

Less common side effects are:

- Acne
- Less sexual desire
- Bloating or fluid retention
- Blotchy darkening of the skin, especially on the face
- High blood sugar, especially in women who already have diabetes
- High fat (cholesterol, triglyceride) levels in the blood
- Depression, especially if you have had depression in the past. Call your healthcare provider immediately if you have any thoughts of harming yourself
- Problems tolerating contact lenses
- Weight gain

This is not a complete list of possible side effects. Talk to your healthcare provider if you develop any side effects that concern you. You may report side effects to the FDA at 1-800-FDA-1088.

No serious problems have been reported from a birth control pill overdose, even when accidentally taken by children.

Do birth control pills cause cancer?

Birth control pills do not seem to cause breast cancer. However, if you have breast cancer now, or have had it in the past, do not use birth control pills because some breast cancers are sensitive to hormones.

Women who use birth control pills may have a slightly higher chance of getting cervical cancer. However, this may be due to other reasons such as having more sexual partners.

What should I know about my period when taking Taytulla?

Irregular vaginal bleeding or spotting may occur while you are taking Taytulla. Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding, which is a flow much like a regular period. Irregular bleeding occurs most often during the first few months of oral contraceptive use, but may also occur after you have been taking the pill for some time. Such bleeding may be temporary and usually does not indicate any serious problems. It is important to continue taking your pills on schedule. If the bleeding occurs in more than one cycle, is unusually heavy, or lasts for more than a few days, call your healthcare provider.

Some women may not have a menstrual period but this should not be cause for alarm as long as you have taken the pills according to direction.

What if I miss my scheduled period when taking Taytulla?

It is not uncommon to miss your period. However, if you go two or more months in a row without a period, or you miss your period after a month where you did not take all your pills correctly, call your healthcare provider because you may be pregnant. Also notify your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. Stop taking Taytulla if you are pregnant.

Need more information?

- This summary contains important risk information about Taytulla. The information provided here is not comprehensive, and is not meant to take the place of your healthcare provider's instructions. To learn more, talk about Taytulla with your healthcare provider or pharmacist.
- The FDA-approved product labeling can be found at www.taytulla.com or call 1-800-678-1605.

Distributed by: Allergan USA, Inc., Madison, NJ 07940

© 2019 Allergan. All rights reserved.

Allergan® and its design are trademarks of Allergan, Inc. Taytulla® and its design are registered trademarks of Allergan Pharmaceuticals International Limited.

Based on TAY92483-v3-F-10/19

TAY105570-v3 10/19