# It's finally here: the first and only FDA-approved oral softgel testosterone undecanoate (TU)[1,2]

## Indication

JATENZO® (testosterone undecanoate) capsules, CIII, is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

## Limitation of use

Safety and efficacy of JATENZO in males less than 18 years old have not been established.

## Select Important Safety Information

### WARNING: INCREASES IN BLOOD PRESSURE

- **JATENZO can cause blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death.**
- **Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits of JATENZO outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease on treatment.**
- **Due to this risk, use JATENZO only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

**Please see Important Safety Information, including BOXED WARNING on increases in blood pressure, on page 8, and full Prescribing Information.**

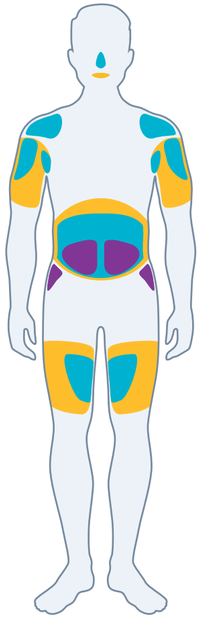
**JATENZO®**
**(testosterone undecanoate)**
**Capsules CIII**

**For men with hypogonadism due to certain medical conditions**

# For years you've been replacing his testosterone.

## It's time to consider replacing the way it's delivered.

Have you ever thought about an oral option? Twice-daily JATENZO, the first and only FDA-approved oral TU, is available for appropriate adult males with hypogonadism.[1,2]



Gel/Topical Solution

Patch

Injection/Implant

## Select Important Safety Information

### CONTRAINDICATIONS

JATENZO is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate, in women who are pregnant, in men with a known hypersensitivity to JATENZO or its ingredients, or in men with hypogonadal conditions that are not associated with structural or genetic etiologies as JATENZO has not been established for these conditions and there is a risk of increased blood pressure with JATENZO that can increase the risk of MACE.

**Please see Important Safety Information, including BOXED WARNING on increases in blood pressure, on page 8, and full Prescribing Information.**

# A unique formulation for oral testosterone delivery

### FORMULATED AS A LIPOPHILIC TESTOSTERONE PRODRUG

- JATENZO bypasses first-pass hepatic metabolism without alkylation[1,3]
- No liver toxicity-related events observed with JATENZO in clinical trials[1,3]
- JATENZO is not known to cause hepatic adverse events[1]
  - Patients should report any signs or symptoms of hepatic dysfunction (eg, jaundice). If these occur, promptly discontinue JATENZO while the cause is evaluated

### DESIGNED FOR ORAL DELIVERY

As an oral softgel, JATENZO offers your appropriate patients a treatment option with[4,5]:

- No injection pain, no procedures
- No mess, no drying time
- No transference to women/kids
- No skin irritation
- No gum irritation/disorders
- No nasal irritation

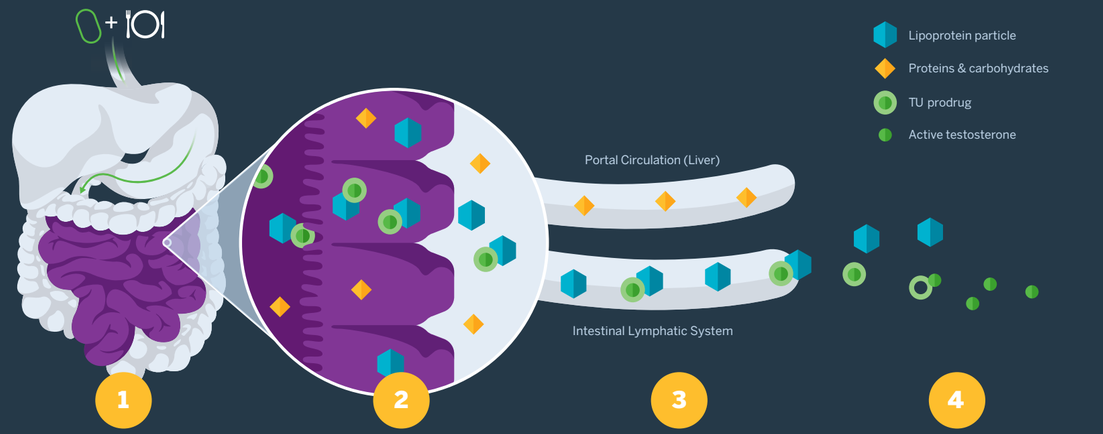
## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

JATENZO can increase blood pressure, which can increase the risk of MACE, with greater risk in patients with established cardiovascular disease or risk factors for cardiovascular disease. Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled. Monitor blood pressure approximately 3 weeks after initiating, increasing the dose, and periodically while on JATENZO, and treat any new or exacerbations of hypertension. Re-evaluate benefits and risks of continued treatment with JATENZO in patients who develop cardiovascular risk factors or disease. JATENZO is contraindicated in men with hypogonadal conditions such as "age-related hypogonadism" because the efficacy of JATENZO has not been established for these conditions and the increases in BP can increase the risk of MACE.

JATENZO®
(testosterone undecanoate)
Capsules CII

# Pharmacokinetics[1,3,6]




**1 TAKEN ORALLY WITH FOOD**

Each JATENZO softgel contains TU, a prodrug formed by attaching a fatty acid to testosterone, which the body naturally cleaves off to release testosterone.

**2 CARRIED BY LIPOPROTEINS INTO LYMPHATICS**

Once in the intestine, this lipophilic prodrug combines with lipoprotein particles, allowing absorption into the intestinal lymphatic system. In contrast, carbohydrates and proteins are absorbed into the portal circulation.

**3 AVOIDS FIRST-PASS HEPATIC METABOLISM**

JATENZO passes into the intestinal lymphatic system (therefore bypassing the liver) as testosterone awaits activation.

**4 RELEASE OF ACTIVE TESTOSTERONE IN CIRCULATION**

After TU releases from lipoprotein particle, endogenous esterases liberate testosterone from TU. Fatty acid is metabolized like dietary fatty acids.

## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

Polycythemia may require a lower dose or discontinuation of JATENZO. Check hematocrit prior to initiation and every 3 months while a patient is on JATENZO and if hematocrit becomes elevated, stop JATENZO until hematocrit decreases to an acceptable level. If hematocrit increases after JATENZO is restarted, stop permanently.

**Please see Important Safety Information, including BOXED WARNING on increases in blood pressure, on page 8, and full Prescribing Information.**

## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

Some studies, but not all, have reported an increased risk of major adverse cardiovascular events (MACE) in association with use of testosterone replacement therapy in men. Long-term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men. Patients should be informed of this possible risk when deciding whether to use or to continue to use JATENZO. JATENZO can increase blood pressure, which can increase the risk of MACE.

JATENZO®
(testosterone undecanoate)
Capsules CIII

# Evaluating efficacy and safety in the phase 3 inTUne study[1]

**JATENZO WAS EVALUATED AMONG 166 ADULT, HYPOGONADAL MEN IN A 4-MONTH, OPEN-LABEL STUDY**


**STARTING DOSE**

237 mg twice daily (BID) with meals

**DOSE ADJUSTMENTS**

- Adjusted on Days 21 and 56 (minimum 158 mg BID; maximum 396 mg BID)
- Based on average testosterone concentration obtained over 24 hours post-morning dose

**PRIMARY ENDPOINT**

Patients (%) with mean plasma total testosterone concentration ($C_{avg}$) over 24 hours within the normal eugonadal range (plasma levels 252-907 ng/dL) on the final pharmacokinetic (PK) visit of the study

**SECONDARY ENDPOINTS**

Patients (%) with a maximum total testosterone concentration ($C_{max}$) above 3 predetermined limits: 1) ≤1500 ng/dL; 2) 1800-2500 ng/dL; 3) >2500 ng/dL

inTUne=**in**vestigational **t**estosterone **un**decanoat**e**.

## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

Monitor patients with benign prostatic hyperplasia (BPH) treated with androgens due to an increased risk for worsening signs and symptoms of BPH. Patients treated with androgens may be at increased risk for prostate cancer and should be evaluated prior to initiating and during treatment with androgens. Monitor prostate-specific antigen (PSA) levels periodically.

Postmarketing reports of venous thromboembolic events (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), have been reported in patients using testosterone replacement products like JATENZO. Evaluate patients with signs or symptoms consistent with DVT or PE and, if a VTE is suspected, discontinue JATENZO and initiate appropriate workup and management.

**Please see Important Safety Information, including BOXED WARNING on increases in blood pressure, on page 8, and full Prescribing Information.**

# Baseline demographics for the inTUne study[3]

| | |
|---|---|
| **AGE, MEAN YEARS** | 51.6 |
| **RACE** | |
| NATIVE AMERICAN OR ALASKA NATIVE | 0 |
| ASIAN | 3 (1.8%) |
| AFRICAN AMERICAN OR BLACK | 29 (17.5%) |
| CAUCASION | 133 (80.1%) |
| OTHER | 1 (0.6%) |
| **BMI (KG/M²)** | 31.8 |
| **SERUM TESTOSTERONE (NG/DL)** | 190.2 |
| **DURATION OF HYPOGONADISM (MEAN YEARS)** | 5.9 |
| **TYPE 1 OR TYPE 2 DIABETES, %** | 24.1 |
| **HISTORY OF HYPERTENSION, %** | 52.4 |

**Key inclusion criteria[3]**

- Men 18 to 65 years of age, with a clinical diagnosis of hypogonadism
- Signs/symptoms consistent with hypogonadism for testosterone-naive subjects
- History of signs/symptoms for subjects who had received prior treatment
- Hypogonadal serum testosterone levels (2 morning total testosterone values <300 ng/dL)
- Naive to TRT or washed out of prior TRTs
- Stable doses of thyroid hormone and adrenal replacement hormones in subjects on replacement therapy for hypopituitarism or multiple endocrine deficiencies

TRT=testosterone replacement therapy.

## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. If abuse is suspected, check testosterone levels to ensure they are in therapeutic range. Counsel patients concerning the serious adverse reactions associated with abuse of testosterone and anabolic androgenic steroids. Conversely, consider the possibility of testosterone and anabolic androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.

JATENZO®
(testosterone undecanoate)
Capsules CII

# Efficacy results from the inTUne study (primary endpoint)[1]

**% JATENZO patients in normal eugonadal range** 87.3%

- The percentage of patients in the eugonadal range exceeded FDA target of 75%; therefore, the efficacy criteria were satisfied and the study met its primary endpoint[3]
- In PK studies, steady state testosterone concentration was achieved by Day 7 and was stable over an extended time period (>9 months)[7,8]

## In the JATENZO group, testosterone levels were within normal eugonadal range at the end of the study (mean ± SD)[1]*

- Serum testosterone $C_{avg}$ = 489 ± 155 ng/dL (normal eugonadal range: 306-1101 ng/dL)
- Plasma testosterone $C_{avg}$ = 403 ± 128 ng/dL (normal eugonadal range: 252-907 ng/dL for blood collected in NaF-EDTA tubes)

**Note that the testosterone concentrations were not measured in serum but the effects of different sample preparation conditions were accounted for in data analysis of the results shown here. The titration scheme for use in clinical practice is based on serum total testosterone.**

*In the inTUne study, testosterone concentrations were measured in plasma isolated from blood collected into NaF-EDTA tubes. NaF was used to limit ex vivo conversion of TU to testosterone, which could artefactually raise measured testosterone levels. In a typical clinical setting, testosterone concentrations are measured in serum isolated from blood collected in plain tubes. To account for the lower testosterone concentrations measured in plasma vs serum, a conversion factor of 1.214 was determined and used to approximate the equivalent mean serum concentration of 489 ± 155 ng/dL from the mean NaF-EDTA plasma testosterone value of 403 ± 128 ng/dL in the inTUne study.[1,3,9]

## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

JATENZO is not indicated for use in women.

Large doses of androgens can suppress spermatogenesis by feedback inhibition of pituitary FSH. Inform patients of this risk before prescribing JATENZO.

# Established safety profile[1]

**NUMBER (%) OF PATIENTS WITH ADVERSE REACTIONS ≥2% IN A 4-MONTH STUDY WITH JATENZO**

| | OVERALL (N=166) |
|---|---|
| HEADACHE | 8 (4.8%) |
| HEMATOCRIT INCREASED | 8 (4.8%) |
| HYPERTENSION | 6 (3.6%) |
| HIGH-DENSITY LIPOPROTEIN DECREASED | 5 (3.0%) |
| NAUSEA | 4 (2.4%) |

Three patients (1.8% of 166) had adverse reactions that led to premature discontinuation from the study, including rash (n=1) and headache (n=2).

**Adverse reactions were reported in >2% of patients in all phase 2 and 3 JATENZO trials combined (N=569):**

- Polycythemia, diarrhea, dyspepsia, eructation, peripheral edema, nausea, increased hematocrit, headache, prostatomegaly, and hypertension

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JATENZO® (testosterone undecanoate) Capsules CII

# Giving him a softgel oral TRT, taken twice daily with food[1]

## JATENZO IS DESIGNED TO PROVIDE BIOAVAILABILITY WITHOUT REQUIRING HIGH-FAT MEALS[3]

- Take JATENZO with food once in the morning and once in the evening[1]
- Individualize the dosage of JATENZO based on the patient's serum testosterone concentration response to the drug[1]


158 mg BID

198 mg BID

316 mg BID
(two 158 mg softgels)

396 mg BID
(two 198 mg softgels)

**In the inTUne study, 72% of patients titrated up from the 237 mg starting dose[3]***

*JATENZO was taken orally at a starting dose of 237 mg twice daily with meals. The dose was adjusted on Days 21 and 56 between a minimum of 158 mg twice per day and a maximum of 396 mg twice per day on the basis of the average testosterone concentration obtained over 24 hours post-morning dose. Data shown represent the percentage of patients on each JATENZO dose at the end of the study. Of the 155 patients, 39 did not require dose adjustment, 52 required 1 dose adjustment, and 64 required 2 dose adjustments.[1,3]

## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

Prolonged use of high doses of methyltestosterone has been associated with serious hepatic adverse events. JATENZO is not known to cause these adverse events; however, patients should be instructed to report any signs of hepatic dysfunction and JATENZO should be discontinued while the cause is evaluated.

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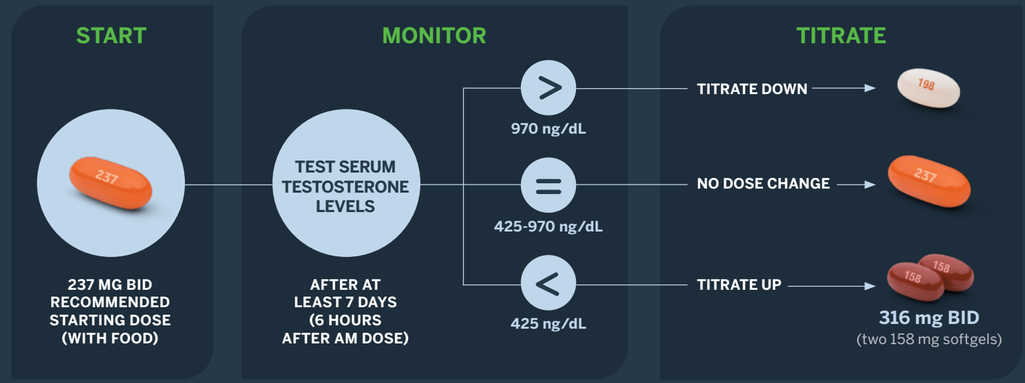
# Helping him find his personalized dose[1]

## FOR EXAMPLE, WHEN STARTING WITH THE RECOMMENDED DOSE:




For specific instruction on dosing and titration, please see the Prescribing Information.

## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

Androgens, including JATENZO, may promote retention of sodium and water. Edema, with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.

JATENZO®
(testosterone undecanoate)
Capsules CII

# How to write his prescription[1]

**FOR THE RECOMMENDED STARTING DOSE OF 237 MG**

**JATENZO 237 mg caps**
**TAKE 1 CAP BID PO WITH FOOD**
**DISPENSE: 60**

For specific instruction on dosing and titration, please see the Prescribing Information.

**FOR WHEN YOU TITRATE UP TO 316 MG DOSE**

**JATENZO 158 mg caps**
**TAKE 2 CAPS BID PO WITH FOOD**
**DISPENSE: 120**

**FOR WHEN YOU TITRATE UP TO 396 MG DOSE**

**JATENZO 198 mg caps**
**TAKE 2 CAPS BID PO WITH FOOD**
**DISPENSE: 120**

**FOR WHEN YOU TITRATE DOWN TO 198 MG DOSE**

**JATENZO 198 mg caps**
**TAKE 1 CAP BID PO WITH FOOD**
**DISPENSE: 60**

**FOR WHEN YOU TITRATE DOWN TO 158 MG DOSE**

**JATENZO 158 mg caps**
**TAKE 1 CAP BID PO WITH FOOD**
**DISPENSE: 60**

## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

Gynecomastia may develop and persist in patients being treated for hypogonadism.

The treatment of hypogonadal men with testosterone may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung disease.

**Please see Important Safety Information, including BOXED WARNING on increases in blood pressure, on page 8, and full Prescribing Information.**

# Offer him savings from the start

**JATENZO GO**


**ELIGIBLE PATIENTS WITH COMMERCIAL INSURANCE MAY PAY AS LITTLE AS $0 FOR THEIR MONTHLY PRESCRIPTION OF JATENZO.***

While waiting for insurance coverage verification and prior authorization appeals, the JATENZO GO program can help patients get started by offering their first prescription for free.*

Restrictions may apply. Up to $2,000 maximum benefit per calendar year.

**To learn more or download a Savings Card online, visit JATENZO.com.**

*Eligibility criteria and limitations apply. This offer is valid in the United States and Puerto Rico. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. See JATENZO.com for more details.

**JATENZO®**
**(testosterone undecanoate)**
**Capsules CII**

## INDICATION

JATENZO® (testosterone undecanoate) capsules, CIII, is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

### Limitation of use

Safety and efficacy of JATENZO in males less than 18 years old have not been established.

## IMPORTANT SAFETY INFORMATION

### WARNING: INCREASES IN BLOOD PRESSURE

- **JATENZO can cause blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death.**
- **Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits of JATENZO outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease on treatment.**
- **Due to this risk, use JATENZO only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

## CONTRAINDICATIONS

JATENZO is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate, in women who are pregnant, in men with a known hypersensitivity to JATENZO or its ingredients, or in men with hypogonadal conditions that are not associated with structural or genetic etiologies as JATENZO has not been established for these conditions and there is a risk of increased blood pressure with JATENZO that can increase the risk of MACE.

## WARNINGS AND PRECAUTIONS

- JATENZO can increase blood pressure, which can increase the risk of MACE, with greater risk in patients with established cardiovascular disease or risk factors for cardiovascular disease. Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled. Monitor blood pressure approximately 3 weeks after initiating, increasing the dose, and periodically while on JATENZO, and treat any new or exacerbations of hypertension. Re-evaluate benefits and risks of continued treatment with JATENZO in patients who develop cardiovascular risk factors or disease. JATENZO is contraindicated in men with hypogonadal conditions such as "age-related hypogonadism" because the efficacy of JATENZO has not been established for these conditions and the increases in BP can increase the risk of MACE.
- Polycythemia may require a lower dose or discontinuation of JATENZO. Check hematocrit prior to initiation and every 3 months while a patient is on JATENZO and if hematocrit becomes elevated, stop JATENZO until hematocrit decreases to an acceptable level. If hematocrit increases after JATENZO is restarted, stop permanently.
- Some studies, but not all, have reported an increased risk of major adverse cardiovascular events (MACE) in association with use of testosterone replacement therapy in men. Long-term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men. Patients should be informed of this possible risk when deciding whether to use or to continue to use JATENZO. JATENZO can increase blood pressure, which can increase the risk of MACE.
- Monitor patients with benign prostatic hyperplasia (BPH) treated with androgens due to an increased risk for worsening signs and symptoms of BPH. Patients treated with androgens may be at increased risk for prostate cancer and should be evaluated prior to initiating and during treatment with androgens. Monitor prostate-specific antigen (PSA) levels periodically.
- Postmarketing reports of venous thromboembolic events (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), have been reported in patients using testosterone replacement products like JATENZO. Evaluate patients with signs or symptoms consistent with DVT or PE and, if a VTE is suspected, discontinue JATENZO and initiate appropriate workup and management.

## WARNINGS AND PRECAUTIONS *(continued)*

- Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. If abuse is suspected, check testosterone levels to ensure they are in therapeutic range. Counsel patients concerning the serious adverse reactions associated with abuse of testosterone and anabolic androgenic steroids. Conversely, consider the possibility of testosterone and anabolic androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.
- JATENZO is not indicated for use in women.
- Large doses of androgens can suppress spermatogenesis by feedback inhibition of pituitary FSH. Inform patients of this risk before prescribing JATENZO.
- Prolonged use of high doses of methyltestosterone has been associated with serious hepatic adverse events. JATENZO is not known to cause these adverse events; however, patients should be instructed to report any signs of hepatic dysfunction and JATENZO should be discontinued while the cause is evaluated.
- Androgens, including JATENZO, may promote retention of sodium and water. Edema, with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.
- Gynecomastia may develop and persist in patients being treated for hypogonadism.
- The treatment of hypogonadal men with testosterone may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung disease.
- Changes in the serum lipid profile may require dose adjustment of lipid-lowering drugs or discontinuation of testosterone therapy. Monitor the lipid profile periodically, particularly after starting testosterone therapy.
- Use JATENZO with caution in cancer patients at risk of hypercalcemia. Monitor serum calcium concentration regularly during treatment with JATENZO in these patients.
- Androgens, including JATENZO, may decrease concentrations of thyroxine-binding globulin, resulting in decreased total T4 serum concentrations and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.
- Depression and suicidal ideation have been reported in patients treated with JATENZO in clinical trials. Advise patients and caregivers to seek medical attention for manifestations of new-onset or worsening depression, suicidal ideation or behavior, anxiety, or other mood changes.

## ADVERSE EVENTS

The most common adverse events of JATENZO (incidence ≥2%) are headache (5%), increased hematocrit (5%), hypertension (4%), decreased HDL (3%), and nausea (2%).

## DRUG INTERACTIONS

- JATENZO can cause changes in insulin sensitivity or glycemic control. Androgens may decrease blood glucose and may require a decrease in the dose of antidiabetic medications.
- Anticoagulant activity may be affected by androgens. More frequent monitoring of international normalized ratio (INR) and prothrombin time are recommended in patients taking warfarin, especially at initiation and termination of androgen therapy.
- Use of testosterone and corticosteroids concurrently may increase fluid retention and requires monitoring in patients with cardiac, renal, or hepatic disease.
- Some prescription and nonprescription analgesic cold medications contain drugs known to increase blood pressure and concomitant use of these medications with JATENZO may lead to additional increases in blood pressure.

## USE IN SPECIFIC POPULATIONS

The safety and efficacy of JATENZO in pediatric patients less than 18 years old have not been established. Improper use may result in acceleration of bone age and premature closure of epiphyses.

There have not been sufficient numbers of geriatric patients involved in controlled clinical studies utilizing JATENZO to determine whether efficacy or safety in those over 65 years of age differs from younger subjects. There is insufficient long-term safety data in geriatric patients utilizing JATENZO to assess the potentially increased risk of cardiovascular disease and prostate cancer.

**Please see full Prescribing Information, including BOXED WARNING on increases in blood pressure.**

### References


1. JATENZO (testosterone undecanoate) [prescribing information]. Clarus Therapeutics, Inc.
2. US Food & Drug Administration. FDA Approved Drug Products. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206089. Accessed April 15, 2020.
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8. Data on file. Clinical Study Report: CLAR-09007. Clarus Therapeutics, Inc.
9. Data on file. Clinical Study Report: CLAR-18019. Clarus Therapeutics, Inc.


JATENZO®
(testosterone undecanoate)
Capsules CIII

# Let's help him take the first step

## GIVE HIM JATENZO, THE ORAL TRT OPTION HE NEVER HAD

The **first and only FDA-approved oral softgel** testosterone undecanoate[1,2]

**Avoids certain administration challenges:** no injection pain, no procedures, no mess, no transfer risk, no irritation[4,5]

Eligible patients with commercial insurance may **pay as little as $0 for their monthly prescription of JATENZO***

**When prescribing, remember the recommended starting dose: 237 mg caps; take 1 cap BID PO with food[1]**

*Eligibility criteria and limitations apply. See JATENZO.com for more details.

**To see if JATENZO may be right for your patients, visit JATENZO.com.**

## Select Important Safety Information

### WARNINGS AND PRECAUTIONS

Changes in the serum lipid profile may require dose adjustment of lipid-lowering drugs or discontinuation of testosterone therapy. Monitor the lipid profile periodically, particularly after starting testosterone therapy.

**Please see Important Safety Information, including BOXED WARNING on increases in blood pressure, on page 8, and full Prescribing Information.**

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(testosterone undecanoate)
Capsules C-III