



# Isotretinoin has joined the Mayne lineup!

Introducing a new way to prescribe generic ABSORICA® (isotretinoin) capsules for your patients with severe recalcitrant nodular acne

#### **Indications and Usage:**

Isotretinoin Capsules, USP are indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, Isotretinoin Capsules, USP are reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

#### **Limitations of Use:**

If a second course of Isotretinoin Capsules, USP therapy is needed, it is not recommended before a two-month waiting period because the patient's acne may continue to improve following a 15 to 20-week course of therapy.

#### **IMPORTANT SAFETY INFORMATION**

##### **WARNING: EMBRYO-FETAL TOXICITY – CONTRAINDICATED IN PREGNANCY**

Isotretinoin Capsules, USP can cause severe life-threatening birth defects and is contraindicated in pregnancy. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking any amount of Isotretinoin Capsules, USP even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining prenatally whether an exposed fetus has been affected. If pregnancy occurs, discontinue Isotretinoin Capsules, USP immediately and refer the patient to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Because of the risk of embryo-fetal toxicity, Isotretinoin Capsules, USP is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the iPLEDGE® REMS.

Important Safety Information continued throughout. Please see full Prescribing Information enclosed for Boxed Warning, Contraindications, and other important Warnings and Precautions.

**Learn more inside!**

**Isotretinoin  
Capsules, USP**

# Isotretinoin Capsules, USP

## Your patients have a choice

An effective and affordable option for treating your patients with severe recalcitrant nodular acne

### Do you have a patient who may benefit from Isotretinoin for the treatment of their severe recalcitrant nodular acne?

Mayne now has a generic Isotretinoin that offers the therapeutic equivalence of ABSORICA® (isotretinoin).<sup>1</sup>

- **Therapeutic equivalence code AB2** compared to ABSORICA® means your patient can receive the same clinical outcome as the brand<sup>1</sup>
- **Food flexibility** means our Isotretinoin can be taken regardless of meals, with no clinically significant impact on absorption<sup>2</sup>
- **Four strengths** allows you to prescribe the options your patients need<sup>2</sup>



**Therapeutic Equivalent  
of ABSORICA®**

**TE code AB2**

### IMPORTANT SAFETY INFORMATION (CON'T) CONTRAINDICATIONS

**Pregnancy:** Isotretinoin Capsules, USP are contraindicated in pregnancy.

**Hypersensitivity:** Isotretinoin Capsules, USP are contraindicated in patients with hypersensitivity to isotretinoin (or Vitamin A, given the chemical similarity to isotretinoin) or to any of its components (anaphylaxis and other allergic reactions have occurred).

#### WARNINGS AND PRECAUTIONS

**Psychiatric Disorders:** Isotretinoin Capsules, USP may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. Prior to and during therapy, assess for these conditions.

Patients should immediately stop Isotretinoin Capsules, USP and promptly contact their prescriber if they develop depression, mood disturbance, psychosis, or aggression. Discontinuation of Isotretinoin Capsules, USP may be insufficient; further evaluation may be necessary such as a referral to a mental healthcare professional.

**Important Safety Information continued throughout. Please see full Prescribing Information enclosed for Boxed Warning, Contraindications, and other important Warnings and Precautions.**

#### Intracranial Hypertension (Pseudotumor Cerebri):

Isotretinoin use has been associated with cases of intracranial hypertension (pseudotumor cerebri), some of which involved concomitant use of tetracyclines. Concomitant treatment with tetracyclines should therefore be avoided with Isotretinoin Capsules, USP use.

**Serious Skin Reactions:** There have been postmarketing reports of erythema multiforme and severe skin reactions [e.g., Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN)] associated with isotretinoin use. These reactions may be serious and result in death, life-threatening events, hospitalization, or disability. Patients should be monitored closely for severe skin reactions, and Isotretinoin Capsules, USP should be discontinued if they occur.

**Acute Pancreatitis:** Acute pancreatitis has been reported with isotretinoin use in patients with either elevated or normal serum triglyceride levels. In rare instances, fatal hemorrhagic pancreatitis has been reported. If symptoms of pancreatitis occur, the patient should discontinue Isotretinoin Capsules, USP and seek medical attention.



Offering **excellent copay** and **cash pay support**  
Patients may pay as little as **\$0\***

# Your patients deserve access to treatment

## Our generic Isotretinoin may help

- ▶ Prescribing a generic Isotretinoin with a therapeutic equivalence that can provide the same outcome as the branded product may help your patients get the treatment they need.

**In addition to excellent access, our Isotretinoin is available in four strengths to fit your patients' needs<sup>2</sup>**

10 mg	20 mg
30 mg	40 mg

Isotretinoin dosing is based on weight. See the enclosed Prescribing Information for more information.

## Our Isotretinoin may be taken with or without food<sup>2</sup>

\*Restrictions and limitations apply. Please see Complete Terms, Conditions and Eligibility Criteria at <https://www.maynepharma.com/legal/co-pay-card/>. Out of pocket costs may vary.

### IMPORTANT SAFETY INFORMATION (CON'T)

**Lipid Abnormalities:** Elevations of serum triglycerides above 800 mg/dL have been reported with isotretinoin use. These lipid changes were reversible upon isotretinoin capsule cessation. Some patients have been able to reverse triglyceride elevation by reduction in weight and restriction of dietary fat and alcohol while continuing isotretinoin or through dosage reduction. The cardiovascular consequences of hypertriglyceridemia associated with isotretinoin are unknown.

**Hearing Impairment:** Impaired hearing has been reported in patients taking isotretinoin; in some cases, the impairment has been reported to persist after therapy has been discontinued. Mechanism(s) and causality for this reaction have not been established. Patients who experience tinnitus or hearing impairment should discontinue Isotretinoin Capsules, USP treatment and be referred for specialized care for further evaluation.

**Hepatotoxicity:** Clinical hepatitis has been reported with isotretinoin use. Additionally, mild to moderate elevations of liver enzymes have been observed in approximately 15% of individuals treated during clinical trials with isotretinoin

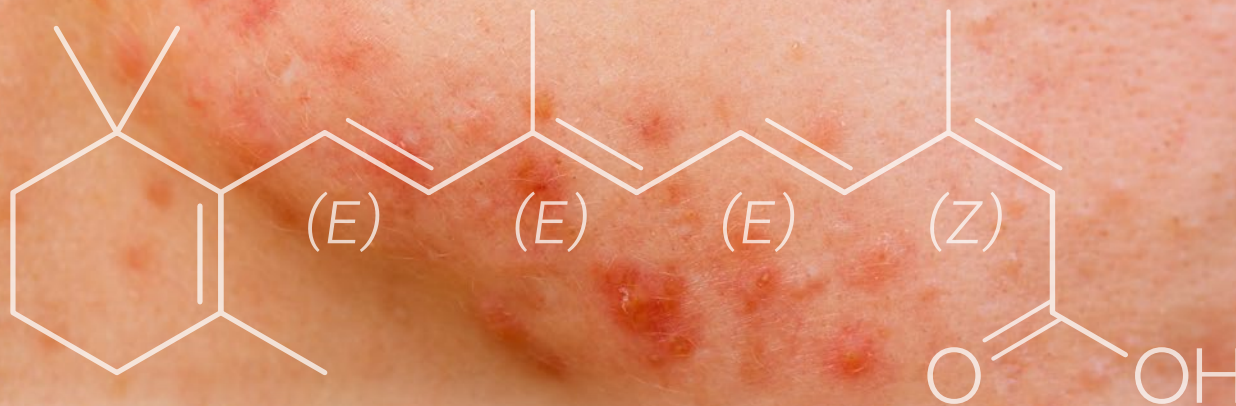
capsules, some of which normalized with dosage reduction or continued administration of the drug. If normalization does not readily occur or if hepatitis is suspected during treatment, Isotretinoin Capsules, USP should be discontinued.

**Inflammatory Bowel Disease:** Isotretinoin has been associated with inflammatory bowel disease (including regional ileitis) in patients without a prior history of intestinal disorders. In some instances, symptoms have been reported to persist after isotretinoin treatment has been stopped. Patients experiencing abdominal pain, rectal bleeding or severe diarrhea should discontinue Isotretinoin Capsules, USP immediately.

**Musculoskeletal Abnormalities:** Effects of multiple courses of isotretinoin on the developing musculoskeletal system are unknown. There is some evidence that long-term, high-dose, or multiple courses of therapy with isotretinoin have more of an effect than a single course of therapy on the musculoskeletal system. It is important that Isotretinoin Capsules, USP be given at the recommended dose for no longer than the recommended duration.

**Important Safety Information continued throughout. Please see full Prescribing Information enclosed for Boxed Warning, Contraindications, and other important Warnings and Precautions.**





## Prescribe as ABSORICA® (isotretinoin) capsules and allow substitutions!

■ Send to your preferred Specialty Pharmacy

Physicians must enroll any patient taking generic ABSORICA® in the iPLEDGE® REMS Program at 1-866-495-0654 or [www.ipledgeprogram.com](http://www.ipledgeprogram.com). This is not the only REMS requirement.

### IMPORTANT SAFETY INFORMATION (CON'T)

**Ocular Abnormalities:** Visual problems should be carefully monitored. If visual difficulties occur, the patient should discontinue Isotretinoin Capsules, USP treatment and obtain an ophthalmological examination.

### ADVERSE REACTIONS

Most common adverse reactions (incidence  $\geq 5\%$ ) are: dry lips, dry skin, back pain, dry eye, arthralgia, epistaxis, headache, nasopharyngitis, chapped lips, dermatitis, increased creatine kinase, cheilitis, musculoskeletal discomfort, upper respiratory tract infection, reduced visual acuity.

### DRUG INTERACTIONS

**Vitamin A:** Isotretinoin Capsules, USP are closely related to vitamin A. Therefore, the use of both vitamin A and Isotretinoin Capsules, USP at the same time may lead to vitamin A related adverse reactions. Patients treated with Isotretinoin Capsules, USP should be advised against taking supplements containing Vitamin A to avoid additive toxic effects.

**Important Safety Information continued throughout. Please see full Prescribing Information enclosed for Boxed Warning, Contraindications, and other important Warnings and Precautions.**

**References:** 1. Data on file. Greenville, NC; Mayne Pharma LLC. 2. Isotretinoin Capsule, USP [package insert]. Greenville, NC: Mayne Pharma; 2021.

**Tetracyclines:** Concomitant treatment with Isotretinoin Capsules, USP and tetracyclines should be avoided because isotretinoin use has been associated with a number of cases of intracranial hypertension (pseudotumor cerebri), some of which involved concomitant use of tetracyclines.

### USE IN SPECIFIC POPULATIONS

There are no data on the presence of isotretinoin in either animal or human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in nursing infants from isotretinoin, advise patients that breastfeeding is not recommended during treatment with Isotretinoin Capsules, USP, and for at least 8 days after the last dose of Isotretinoin Capsules, USP.

These are not all of the possible side effects of Isotretinoin Capsules, USP. To report SUSPECTED ADVERSE REACTIONS, contact Upsher-Smith Laboratories, LLC at 1-855-899-9180 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or iPLEDGE at 1-866-495-0654.

## Learn more today

Ask your Mayne representative about  
Isotretinoin Capsules, USP

## Isotretinoin Capsules, USP



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