PERSERIS® is indicated for the treatment of schizophrenia in adults.

**PERSERIS is designed to support your patients during this pivotal moment in their treatment journey**

# PERSERIS delivers clinically relevant levels from the very first dose[1,2]

## One subcutaneous injection provides treatment for an entire month[1]


- In risperidone-naive patients, establish tolerability with oral risperidone prior to initiating PERSERIS[1]
- Patients who are on stable oral risperidone dosages lower than 3 mg per day or higher than 4 mg per day may not be candidates for PERSERIS[1]
- In patients with renal or hepatic impairment, carefully titrate up to at least 3 mg daily of oral risperidone prior to starting PERSERIS at a dose of 90 mg once monthly[1]
- PERSERIS must be administered by a healthcare provider (HCP)[1]

## IMPORTANT SAFETY INFORMATION

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

**Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. PERSERIS is not approved for the treatment of patients with dementia-related psychosis.**

**CONTRAINDICATIONS:** PERSERIS is contraindicated in patients with a known hypersensitivity to risperidone, its metabolite, paliperidone, or to any of its components. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone or paliperidone.

**See additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING.**

once-monthly
**PERSERIS®**
(risperidone)
for extended-release injectable suspension
**90 mg · 120 mg**

## Support your patients through their injection experience

### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS

**Cerebrovascular Adverse Reactions:** In trials of elderly patients with dementia-related psychosis, there was a significantly higher incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, in patients treated with oral risperidone compared to placebo. PERSERIS is not approved for use in patients with dementia-related psychosis.

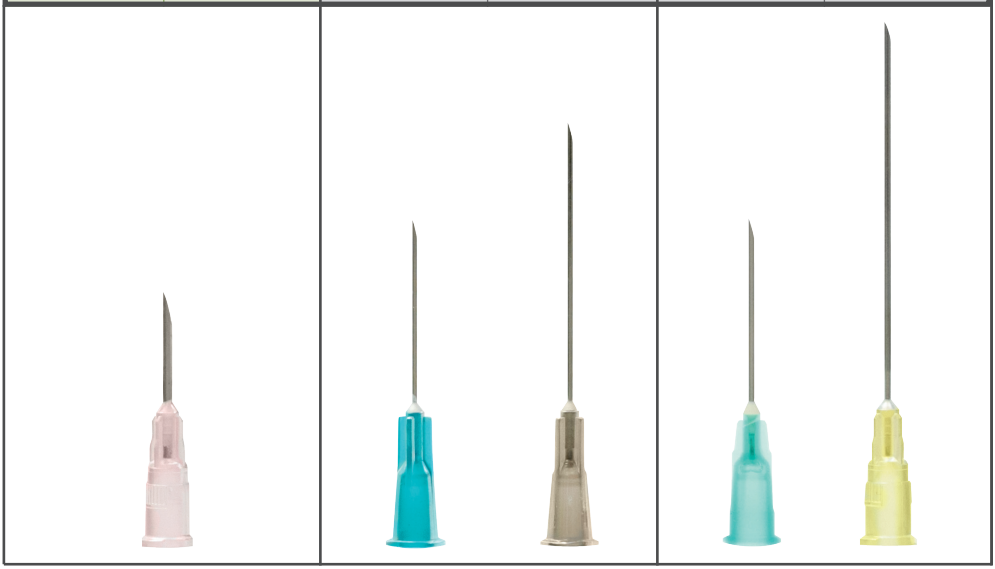
**Neuroleptic Malignant Syndrome (NMS),** a potentially fatal symptom complex, has been reported with antipsychotic medications. Clinical manifestations include hyperpyrexia, muscle rigidity, altered mental status including delirium, and autonomic instability (see full Prescribing Information). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. If NMS is suspected, immediately discontinue PERSERIS and provide symptomatic treatment and monitoring.

**See additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING.**

# PERSERIS® is the first subcutaneous risperidone-containing long-acting injectable (LAI) for adults with schizophrenia[1,3]

## Needle sizes of select LAIs for schizophrenia

| PERSERIS® (risperidone)[1] | | Invega Sustenna® (paliperidone palmitate)[3] | | Risperdal Consta® (risperidone)[4] | |
|---|---|---|---|---|---|
| subcutaneous | | intramuscular | | intramuscular | |
| Gauge | Length | Gauge | Length | Gauge | Length |
| 18 | 5/8″ | 23 | 1″ | 21 | 1″ |
| | | 22 | 1.5″ | 20 | 2″ |



Display not meant to draw comparisons of safety or efficacy.

Needle sizes are the representations of the gauges and lengths outlined in the Prescribing Information of each product as of October 2022.



## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (CONT'D)

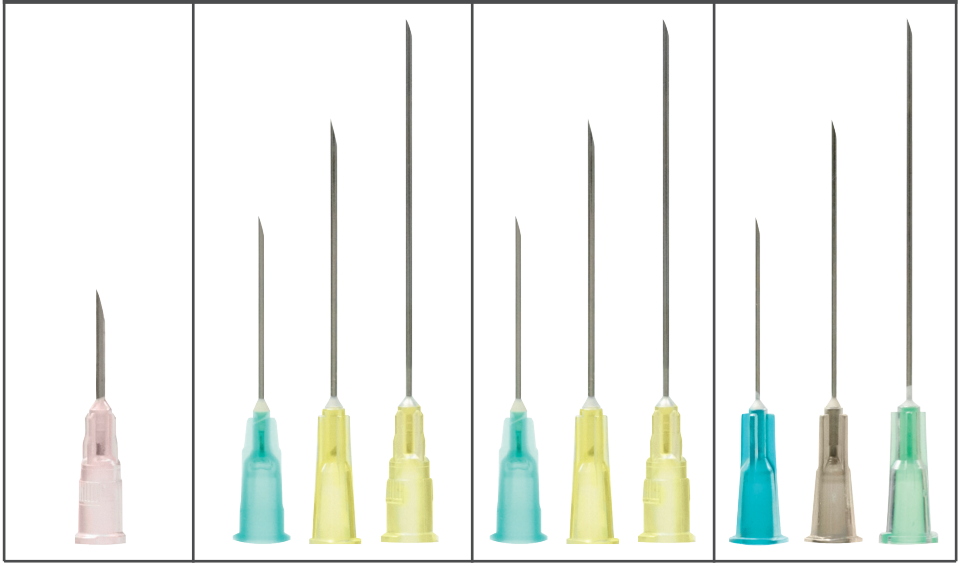
**Tardive Dyskinesia (TD)** may develop in patients treated with antipsychotic drugs. The risk of developing TD and likelihood that it will become irreversible are believed to increase with treatment duration and total cumulative dose. TD can develop after relatively brief treatment periods even at low doses, or after treatment discontinuation. Elderly patients, especially elderly women, appear to be at increased risk, but it is impossible to predict which patients will develop TD. Therefore, PERSERIS should be prescribed in a manner that is most likely to minimize the occurrence of TD. Discontinue treatment if clinically appropriate.

**See additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING.**

# PERSERIS® is the first subcutaneous risperidone-containing long-acting injectable (LAI) for adults with schizophrenia[1,3]

## Needle sizes of select LAIs for schizophrenia (cont'd)

| PERSERIS® (risperidone)[1] | | Aristada® (aripiprazole lauroxil)[5] | | Aristada Initio® (aripiprazole lauroxil)[6] | | Abilify Maintena® (aripiprazole)[7] | |
|---|---|---|---|---|---|---|---|
| subcutaneous | | intramuscular | | intramuscular | | intramuscular | |
| Gauge | Length | Gauge | Length | Gauge | Length | Gauge | Length |
| 18 | 5/8″ | 21 | 1″ | 21 | 1″ | 23 | 1″ |
| | | 20 | 1.5″ | 20 | 1.5″ | 22 | 1.5″ |
| | | 20 | 2″ | 20 | 2″ | 21 | 2″ |



## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (CONT'D)

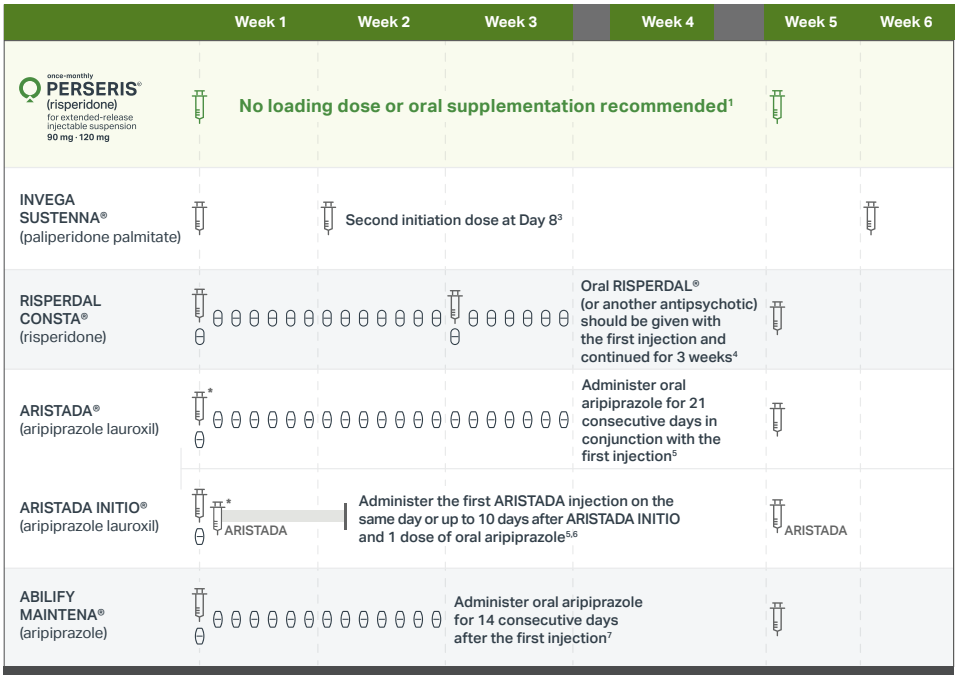
**Metabolic Changes** that may increase cardiovascular/cerebrovascular risk, have been associated with atypical antipsychotics (APs).

- **Hyperglycemia and Diabetes Mellitus (DM),** in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, have been reported in patients treated with APs, including risperidone. Patients with DM who are started on atypical APs, including PERSERIS, should be monitored regularly for worsening of glucose control. Patients at risk for DM (e.g., obesity, family history of diabetes) who are starting treatment with atypical APs, including PERSERIS, should undergo fasting blood glucose (FBG) testing at the beginning of treatment and periodically while treated. Any patient treated with atypical APs, including PERSERIS, should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical APs, including PERSERIS, should undergo FBG testing. In some cases, hyperglycemia has resolved when risperidone was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of risperidone.

# Straightforward initiation



## Dosing regimens of select LAIs for schizophrenia




- In risperidone-naive patients, establish tolerability with oral risperidone prior to initiating PERSERIS[1]
- Patients who are on stable oral risperidone dosages lower than 3 mg per day or higher than 4 mg per day may not be candidates for PERSERIS[1]
- In patients with renal or hepatic impairment, carefully titrate up to at least 3 mg daily of oral risperidone prior to starting PERSERIS at a dose of 90 mg once monthly[1]
- PERSERIS must be administered by an HCP[1]

Before starting an LAI, establish tolerability based on appropriate Prescribing Information instructions.

*Depending on the needs of an individual patient, treatment with ARISTADA can be initiated at a dose of 441 mg, 662 mg, or 882 mg administered monthly; 882 mg administered every 6 weeks; or 1064 mg administered every 2 months.[6]

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (CONT'D)

- **Dyslipidemia** has been observed in patients treated with atypical APs. When initiating PERSERIS, obtain a fasting lipid profile and monitor periodically during treatment.
- **Weight Gain** has been observed with atypical AP use. Monitoring weight is recommended.

**Hyperprolactinemia:** Risperidone elevates prolactin levels, and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents. Hyperprolactinemia may inhibit reproductive function in female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating drugs. Long-standing hyperprolactinemia, when associated with hypogonadism, may lead to decreased bone density in females and males.

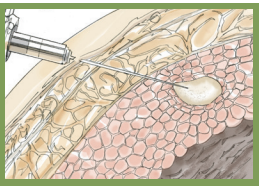
# PERSERIS® features Indivior's proprietary risperidone gel depot delivery system[3]

## How the delivery system works:

**1**

**Subcutaneous injection**

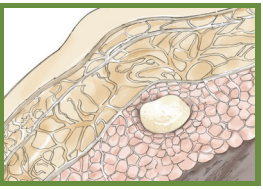
- PERSERIS is injected into subcutaneous tissue in the abdomen or back of upper arm[1]
- Must be administered by an HCP[1]
- Do not administer by any other route[1]



**2**

**Depot formation**

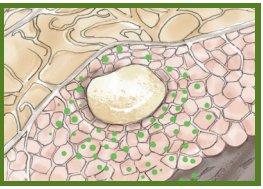
- A risperidone-containing depot is formed on contact with tissue fluids[1,3]



**3**

**Continuous release**

- Risperidone is released on initial depot formation, followed by sustained drug release from the depot over the entire 1-month dosing period[1]



The distribution of risperidone is for illustrative purposes only.
For dosing and administration instructions, please see Section 2 of the full Prescribing Information.

A direct correlation between the delivery system and symptom improvement has not been clinically evaluated.

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (CONT'D)

**Orthostatic Hypotension and Syncope:** Risperidone may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, particularly at treatment initiation, re-initiation, or dose increase. Use with particular caution in patients with known cardiovascular disease, cerebrovascular disease, and conditions which predispose patients to hypotension, and in the elderly and patients with renal or hepatic impairment. Monitor such patients and consider a dose reduction if hypotension occurs.

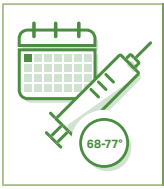
**Falls:** Somnolence, postural hypotension, motor instability, and sensory instability have been reported with the use of antipsychotics, including PERSERIS, which may lead to falls, and consequently, fractures or other fall-related injuries. Assess the risk of falls when initiating treatment and recurrently during treatment.

**Leukopenia, Neutropenia, and Agranulocytosis** have been reported with antipsychotic agents, including risperidone. In patients with history of clinically significant low white blood count (WBC) or absolute neutrophil count (ANC), or history of drug-induced leukopenia or neutropenia, perform a complete blood count frequently during the first few months of therapy. Consider discontinuation at the first sign of clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms/signs of infection; treat promptly if such symptoms/signs occur. Discontinue PERSERIS in patients with ANC <1000/$mm^3$ and follow WBC until recovery.

**Potential for Cognitive and Motor Impairment:** Antipsychotics including PERSERIS may cause somnolence and impair judgment, thinking, and motor skills. Caution patients about operating machinery, including motor vehicles, until they are reasonably certain PERSERIS does not affect them adversely.

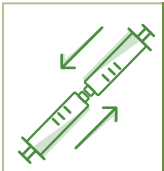
**See additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING.**

## Important steps to get your patients started




**Storage options**

- PERSERIS must be refrigerated (36°F to 46°F) for storage[1]
- It can remain at room temperature (68°F to 77°F) in its original carton for up to 30 days prior to administration[1]
- Discard after 30 days at room temperature[1]



**Reconstitute for use**

- Allow PERSERIS kit to come to room temperature for at least 15 minutes before mixing[1]
- PERSERIS requires thorough mixing to uniformly combine the risperidone powder and delivery system liquid. Refer to full Prescribing Information for detailed instructions[1]

**First-in-market risperidone-containing LAI for subcutaneous administration[1,3]**

- PERSERIS is administered using a 5/8-inch, 18-gauge safety needle[1]
- Following subcutaneous injection, a depot is formed that provides the sustained release of risperidone over the monthly dosing period[1]
- Administration of PERSERIS must be performed by an HCP[1]

• In risperidone-naive patients, establish tolerability with oral risperidone prior to initiating PERSERIS[1]

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (CONT'D)

**Seizures** were observed in risperidone studies in adults with schizophrenia. PERSERIS should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold.

**Dysphagia:** Esophageal dysmotility and aspiration can occur. Use cautiously in patients at risk for aspiration.

**Priapism** has been reported with other risperidone products. Severe priapism may require surgical intervention.

**Body Temperature Regulation:** Atypical antipsychotics may disrupt the body's ability to reduce core body temperature. Use with caution during strenuous exercise, exposure to extreme heat, dehydration, or when taking anticholinergic medications.

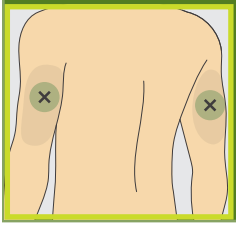
**ADVERSE REACTIONS:** The most common adverse reactions in a clinical trial (≥ 5% and greater than placebo) were increased weight, constipation, sedation/somnolence, pain in extremity, back pain, akathisia, anxiety, and musculoskeletal pain. The most common injection site reactions (≥ 5%) were injection site pain and erythema. This is not a complete list of potential adverse events. Please see the full Prescribing Information for a complete list.

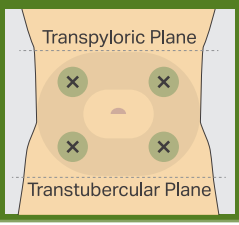
### DRUG INTERACTIONS

- Carbamazepine and other strong CYP3A4 inducers decrease risperidone plasma concentration.
- Fluoxetine, paroxetine, and other strong CYP2D6 inhibitors increase risperidone plasma concentration.
- Use with other CNS drugs or alcohol may increase nervous system disorders.
- PERSERIS may enhance hypotensive effects of hypotensive agents.
- PERSERIS may antagonize the pharmacologic effects of dopamine agonists.
- Dosage change in PERSERIS or methylphenidate may increase risk of extrapyramidal symptoms.

# How to administer PERSERIS® (select steps)

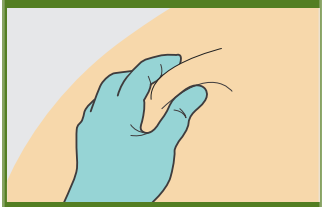
## 1. Select and prepare injection site





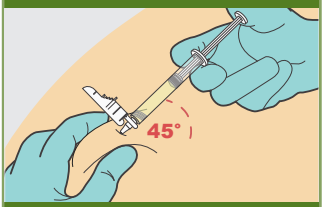

Find adequate subcutaneous tissue in the abdomen or back of upper arm free of skin conditions such as nodules, lesions or excessive pigment. Clean the injection site well with an alcohol pad. To help minimize irritation, rotate injection sites with each monthly injection. Do not inject into an area where the skin is irritated, reddened, bruised, infected or scarred.[1]

## 2. Pinch injection site



Pinch the skin around the injection area. Be sure to pinch enough skin to accommodate the size of the needle. Lift the adipose tissue from the underlying muscle to prevent accidental intramuscular injection.[1]

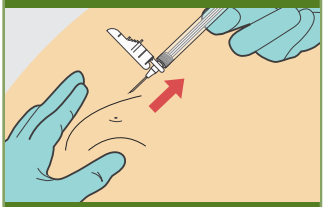
## 3. Inject medication




Insert needle fully into the subcutaneous tissue. Inject the medication slow and steady. PERSERIS is for subcutaneous administration only. Do not inject by any other route.[1]

**NOTE:** Recommended injection angle is 45 degrees, but the actual angle of injection will depend on the amount of subcutaneous tissue.[1]

## 4. Withdraw needle



Withdraw at the same angle used for insertion and release pinched skin. Do not rub the injection area after the injection. If there is bleeding, apply a gauze pad or bandage, but use minimal pressure.[1]

For dosing and administration instructions, please see Section 2 of the full Prescribing Information.

**Watch step-by-step video instructions at www.perserishcp.com/how-to-inject**

- In risperidone-naive patients, establish tolerability with oral risperidone prior to initiating PERSERIS[1]

## IMPORTANT SAFETY INFORMATION

### USE IN SPECIFIC POPULATIONS

**Pregnancy:** PERSERIS may cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare professional if they become or intend to become pregnant during treatment with PERSERIS. Patients exposed to PERSERIS during pregnancy may be registered with the National Pregnancy Registry for Atypical Antipsychotics (**1-866-961-2388** or **http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/**).

**See additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING.**

# Most patients reported little or no injection site pain over the course of the studies[1]

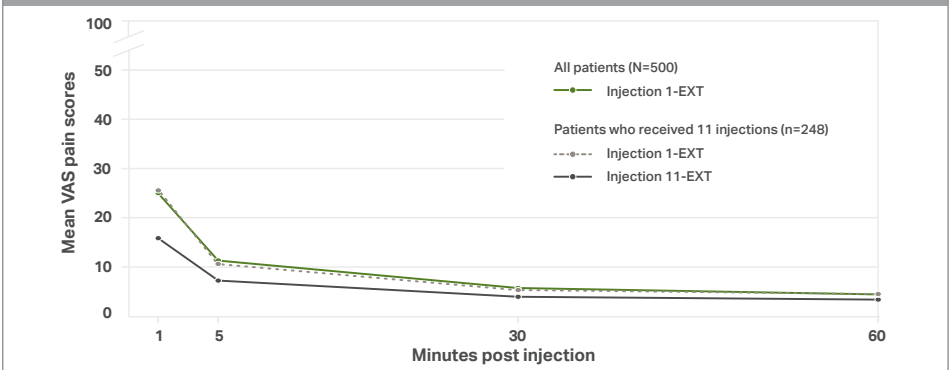


After subcutaneous injection, most patients reported no injection pain (≥75%), no tenderness (≥79%), no erythema (≥92%), and no inflammation (≥88%) after receiving PERSERIS® across the clinical development program.[1]

- Less than 1% of patients reported moderate tenderness at any time point, and 1 patient reported severe tenderness. Additionally, 1 or 2 patients reported cases of moderate pain, erythema, and/or inflammation/swelling[1]
- Injection site pain was measured using a subject-reported Visual Analog Scale (VAS) (0=no pain to 100=unbearably painful)[1]

Injection site pain was measured from the start of the 12-month extension (EXT) study. (Rollover patients received 2 prior injections of PERSERIS in the Phase 3 double-blind study.)[2]

**Injection site pain scores out of 100[2]**




- Initial injection site pain was none or mild for most patients, and decreased over time with subsequent injections of PERSERIS[1]
- Mean injection site pain VAS scores for all patients (N=500) were 11.2 and 5.6 at 5 minutes and 30 minutes post injection 1, respectively[2]
- Mean injection site pain VAS scores for all patients (N=500) 1 minute after injection 1 decreased from 25 to 16 by injection 11 (n=248)[2]

### Injection site reactions occurring in ≥5% of patients

- In an 8-week study, the most common injection site reactions were injection site pain (90 mg: 16%; 120 mg: 22%; placebo: 20%), injection site erythema (90 mg: 6%; 120 mg: 4%; placebo: 5%), and induration/nodule (90 mg: 3%; 120 mg: 3%; placebo: 5%)[2]
- In an open-label extension study, the most common injection site reactions for all patients were injection site pain (13%), injection site nodule (7%), injection site induration (6%), and injection site pruritus (5%)[2]

## IMPORTANT SAFETY INFORMATION

### USE IN SPECIFIC POPULATIONS (CONT'D)

**Lactation:** Infants exposed to risperidone through breastmilk should be monitored for excess sedation, failure to thrive, jitteriness, and extrapyramidal symptoms.

**Pediatric Use:** Safety and effectiveness of PERSERIS have not been established in pediatric patients.

**Renal or Hepatic Impairment:** Carefully titrate on oral risperidone up to at least 3 mg before initiating treatment with PERSERIS at a dose of 90 mg.

**Patients with Parkinson's Disease or dementia with Lewy Bodies** can experience increased sensitivity to risperidone. Manifestations can include confusion, obtundation, postural instability with frequent falls, extrapyramidal symptoms, and clinical features consistent with NMS.

**To report a pregnancy or side effects associated with taking PERSERIS or any safety related information, product complaint, request for medical information, or product query, please contact PatientSafetyNA@indivior.com or 1-877-782-6966.**

PERSERIS® is indicated for the treatment of schizophrenia in adults.

**Designed to support your patients during this pivotal moment in their treatment journey**

# PERSERIS delivers clinically relevant levels from the very first dose[1,2]

- Once-monthly dosing with no loading dose or oral supplementation recommended[1]
- Indivior's proprietary risperidone gel depot delivery system provides patients a steady release of risperidone over a 1-month period[1,3]
- Most patients reported little to no injection site pain over the course of clinical studies[1]

**Scan for more information about PERSERIS** **OR** **Visit www.perserishcp.com/steps-worth-taking**


- In risperidone-naive patients, establish tolerability with oral risperidone prior to initiating PERSERIS[1]
- Patients who are on stable oral risperidone dosages lower than 3 mg per day or higher than 4 mg per day may not be candidates for PERSERIS[1]
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**CONTRAINDICATIONS:** PERSERIS is contraindicated in patients with a known hypersensitivity to risperidone, its metabolite, paliperidone, or to any of its components. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone or paliperidone.

**See accompanying full Prescribing Information including BOXED WARNING.**

**References: 1.** PERSERIS [prescribing information]. North Chesterfield, VA: Indivior Inc. **2.** Data on file. Indivior Inc. North Chesterfield, VA. **3.** Tchobaniouk LV, McAllister EE, Bishop DL, et al. Patient Prefer Adherence. 2019;13:2233-2241. **4.** INVEGA SUSTENNA [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. **5.** RISPERDAL CONSTA [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. **6.** ARISTADA [prescribing information]. Waltham, MA: Alkermes, Inc. **7.** ARISTADA INITIO [prescribing information]. Waltham, MA: Alkermes, Inc. **8.** ABILIFY MAINTENA [prescribing information]. Rockville, MD. Otsuka America Pharmaceutical, Inc.

once-monthly
**PERSERIS®**
(risperidone) for extended-release injectable suspension
**90 mg · 120 mg**

INDIVIOR®