# For patients with Dravet syndrome 2 years of age and older





# Reimagine what's possible with FINTEPLA

#### Indication

- FINTEPLA is a prescription medicine used to treat seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older.
- It is not known if FINTEPLA is safe and effective in children less than 2 years of age.

## **Select Important Safety Information**

#### FINTEPLA can cause serious side effects, including:

Problems with the valves in the heart (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension) have been associated with fenfluramine, the active ingredient in FINTEPLA. Your healthcare provider will do a test called an echocardiogram to check your heart and to evaluate for high blood pressure in the arteries of the lungs before you start taking FINTEPLA, again every 6 months during treatment, and one time 3 to 6 months after you take your last dose of FINTEPLA.

Please see full Important Safety Information on pages 15-19 and full <u>Prescribing Information</u>, including <u>Medication Guide</u>.



# Discover something different



You've worked hard to manage the seizures associated with Dravet syndrome.

At some point, you may have asked yourself, "What else is possible for my loved one's treatment?" If this question has crossed your mind, you may be ready for FINTEPLA—a different approach to seizure management.



#### Check in with yourself

Discussing a change to your loved one's treatment plan with the healthcare team feels like a big step. It can help to have a plan for what you want to talk about. No matter how you're feeling about making a change, it's important to know what your priorities are.

Because each family's experience with Dravet syndrome is unique, the goals you want to reach with a different treatment will be personal, too.

Take a moment to think about your loved one's treatment plan.

What's wor a change?	king well? Wh	nat do I wish	n was diffe	rent? Am I r	eady to ma	ıke
What could	fewer seizure	es mean for	my loved o	ne?		
What could	longer seizur	e-free inter	rvals mean	for our fam	nily?	

## You're in the right place

Whether you feel ready to start FINTEPLA or are just a little curious, this brochure may have the information you're looking for. Let's get started.

# How FINTEPLA can make a difference



In this brochure, you will find some key considerations for talking with your loved one's healthcare team about FINTEPLA in Dravet syndrome.



# FINTEPLA and your loved one's seizures

Clinical studies show that FINTEPLA offered profound seizure reduction and more seizure-free days.

Learn more on pages 4-6



## Safety is our priority

The FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program requires periodic cardiac monitoring via echocardiogram to detect problems with the valves in the heart and high blood pressure in the arteries of the lungs.

Visit <u>Fintepla.com</u> to learn more about safety and the FINTEPLA REMS Program.

Learn more on pages 7-8



# FINTEPLA works with current treatment plans

You may not have to worry about adjusting current antiseizure treatments.

Visit <u>Fintepla.com</u> to watch a video on how FINTEPLA can fit into <u>current treatment plans</u>.

Learn more on page 9



# Enjoy personalized support

Get access to individualized resources and medical expertise through the ONWARD  $^{\text{TM}}$  Support Program.

Learn more on pages 10-11

## **Important Safety Information**

#### FINTEPLA can cause serious side effects, including:

1. Problems with the valves in the heart (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension) have been associated with fenfluramine, the active ingredient in FINTEPLA. Your healthcare provider will do a test called an echocardiogram to check your heart and to evaluate for high blood pressure in the arteries of the lungs before you start taking FINTEPLA, again every 6 months during treatment, and one time 3 to 6 months after you take your last dose of FINTEPLA.



# Patients with Dravet syndrome had fewer seizures with FINTEPLA

**Here's the big picture.** Safety and effectiveness were evaluated in 2 clinical studies in patients with Dravet syndrome. **Study 1** had 117 patients and **Study 2** had 85 patients.

After the original clinical studies, 94% of patients decided to continue with FINTEPLA and participate in an open-label extension study, where they knew they were being treated with FINTEPLA. In total, 341 patients with Dravet syndrome were treated with FINTEPLA in clinical studies.

# Study 1

# FINTEPLA offered profound seizure reduction



Patients took FINTEPLA (0.7 mg/kg/day) or placebo on top of their current antiseizure treatment plans during the study. Results may vary.

## Important Safety Information (continued)

Call your healthcare provider right away if you develop any of these signs and symptoms of heart or lung problems during treatment with FINTEPLA:

- shortness of breath
- tiredness or weakness, especially with increased activity
- lightheadedness or fainting
- swollen ankles or feet

- chest pain
- sensations of a rapid, fluttering heartbeat (palpitations)
- irregular pulse
- bluish color of your lips and skin (cyanosis)

Please see full Important Safety Information on pages 15-19 and full Prescribing Information, including Medication Guide.



# FINTEPLA gave patients more consecutive seizure-free days

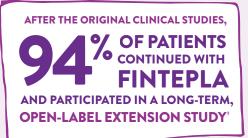
FINTEPLA made a difference for patients whose seizures were not controlled.

Study 1

# FINTEPLA offered more seizure-free days



\*In a clinical study, 50% of patients taking FINTEPLA (0.7 mg/kg/day) had a seizure-free streak lasting at least 21 days. This is compared with 8 days for patients taking placebo.



## FINTEPLA: Long-term results

Throughout this open-label extension study, most patients maintained the seizure reduction they experienced in the clinical studies.

<sup>†</sup>An open-label study means patients knew they were being treated with FINTEPLA and not a placebo.

## Important Safety Information (continued)

Because of the risk of heart valve problems (valvular heart disease) and high blood pressure in arteries of lungs (pulmonary arterial hypertension), FINTEPLA is only available through a restricted program called the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program. Before you or your child receives FINTEPLA, your healthcare provider or pharmacist will make sure you understand how to take FINTEPLA safely. If you have any questions about FINTEPLA, ask your healthcare provider, visit www.FinteplaREMS.com, or call 1-877-964-3649.





As a caregiver, you've seen a lot of scientific data. Sometimes, these data make more sense when you know more about the clinical studies.

# **Understanding Study 1**

Here's a little bit of background about the patients with Dravet syndrome who participated in Study 1:

- >> Patients were between 2 and 18 years old
- >> Patients had uncontrolled seizures (6 or more convulsive seizures over 6 weeks)
- Patients were taking between 1 and 4 antiseizure medicines or treatments during the study
  - included clobazam, valproate, topiramate, vagal nerve stimulation, or a ketogenic diet
  - Patients taking stiripentol were not eligible for this study
- >> Patients were randomly placed into 1 of 2 groups:
  - ♠ The FINTEPLA group had FINTEPLA added to their existing treatment plans
  - The placebo group stayed on their existing treatment plans

## Patients stayed on FINTEPLA

Over 3 years, 341 patients took FINTEPLA in the clinical studies, with **138 patients** taking FINTEPLA for more than 2 years.

The FINTEPLA REMS Program requires that patients be monitored for problems with the valves in the heart and high blood pressure in the arteries of the lungs. In the clinical studies, none of the 341 patients who took FINTEPLA developed these side effects.

## Important Safety Information (continued)

- **2. Decreased appetite and decreased weight.** Decreased appetite and decreased weight are both serious and common side effects of FINTEPLA in people with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS).
  - Your weight should be checked regularly during your treatment with FINTEPLA.
  - Your healthcare provider may need to make changes to your FINTEPLA dose if your weight decreases. In some cases, FINTEPLA may need to be stopped.

Please see full Important Safety Information on pages 15-19 and full Prescribing Information, including Medication Guide.



# The FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program

The FINTEPLA REMS Program was created with **your loved one's safety in mind**. It requires that they have regular heart checkups (echocardiograms) once before starting treatment with FINTEPLA, again every 6 months during treatment, and once 3 to 6 months after their last dose. This helps manage potential safety concerns.

Visit <u>Fintepla.com</u> to watch a video about the FINTEPLA REMS Program.



#### What it is

The FINTEPLA REMS Program is a drug safety program that the US Food and Drug Administration (FDA) requires for certain medicines with serious safety concerns. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are more than the risks. The FDA must approve these steps as part of the REMS Program.



## Why it matters

**FINTEPLA** is available only through the FINTEPLA REMS Program due to the risk of problems with valves in the heart (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension). In the past, some adults who took fenfluramine, the active ingredient in FINTEPLA, developed problems with valves in the heart and high blood pressure in the arteries of the lungs.

The FINTEPLA REMS Program can help to identify any problems before symptoms develop.

None of the 341 patients with Dravet syndrome or 262 patients with LGS who took FINTEPLA during the clinical studies developed problems with their heart valves that caused valvular heart disease or high blood pressure in the arteries of the lungs (pulmonary arterial hypertension), including patients treated for up to 3 years.



## Important Safety Information (continued)

3. Sleepiness, sedation, and lack of energy (lethargy). These are both serious and common side effects of FINTEPLA in people with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS). Taking FINTEPLA with central nervous system (CNS) depressants, including alcohol, may increase sleepiness. Do not drive, operate heavy machinery, or do other dangerous activities until you know how FINTEPLA affects you.



# What does the FINTEPLA REMS Program mean for me?

Because FINTEPLA is only available through the REMS Program, there are a few steps you and your loved one's healthcare team will need to take.

# If you and your loved one's healthcare provider decide to start treatment with FINTEPLA, you will:

- 1. Review and discuss the REMS Patient Guide with your loved one's healthcare provider
  - >> Visit FinteplaREMS.com to read the guide and learn more
- 2. Sign an enrollment form; your loved one's healthcare provider will submit this form for you
- 3. Get an echocardiogram (echo test) for your loved one before receiving FINTEPLA
  - An echo test will help determine how healthy their heart is before starting FINTEPLA
  - You can ask their healthcare provider how ONWARD may be able to help you find a location for an echo test
- 4. Take your loved one for an echo test every 6 months during treatment

If you and your loved one's healthcare provider decide to stop FINTEPLA for any reason, you'll take your loved one for one more echo test 3 to 6 months after stopping treatment.

Visit Fintepla.com to see a video with tips for your loved one's first echo test.

Your healthcare provider will help you understand the steps of the REMS Program and sign up before your loved one starts FINTEPLA.

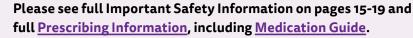
## Important Safety Information (continued)

**4. Like all other antiepileptic drugs, FINTEPLA may cause suicidal thoughts or actions** in a very small number of people (about 1 in 500).

Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- · thoughts about suicide or dying
- trouble sleeping (insomnia)
- attempts to commit suicide
- new or worse irritability
- new or worse depression
- acting aggressive, being angry or violent
- new or worse anxiety

- acting on dangerous impulses
- feeling agitated or restless
- an extreme increase in activity and talking (mania)
- panic attacks
- other unusual changes in behavior or mood







# FINTEPLA and your loved one's treatment routine

# FINTEPLA can be taken with other antiseizure medicines and treatments

and is designed to fit in with your loved one's current treatment plan.

#### Why FINTEPLA fits:

Visit Fintepla.com to see a video that talks about how FINTEPLA can fit into current treatment plans.

- FINTEPLA can be taken by mouth with or without food
- FINTEPLA is compatible with gastric and nasogastric feeding
- Dosing is flexible based on how well your loved one responds to and tolerates FINTEPLA
- FINTEPLA can be taken with other antiseizure medicines and treatments such as vagal nerve stimulation or a ketogenic diet

## Important Safety Information (continued)

#### How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

# FINTEPLA support along the way

Whether you simply have a few questions about FINTEPLA or have a loved one who is about to start treatment, ONWARD provides dedicated one-on-one support to help move you forward.



# Considering FINTEPLA?

ONWARD has resources to help get you going in the right direction.

**FINTEPLA Clinical Nurse Educators (CNEs)** are registered nurses and experts in Dravet syndrome and LGS who answer any questions you have and provide treatment education for families before starting FINTEPLA.\* They can:

- Prepare you for conversations with your loved one's healthcare provider
- Discuss results of the FINTEPLA clinical studies and what they may mean for your family
- Answer your questions about the FINTEPLA REMS Program
- Educate you on financial support programs for access to FINTEPLA treatment and echo tests

\*Clinical Nurse Educators cannot provide medical advice or make treatment recommendations. They can only provide information about FINTEPLA. Decisions regarding your loved one's health and the treatment of their condition should be made with their healthcare provider.



Get in touch with a Clinical Nurse Educator by calling 1-833-GO-DS-LGS (1-833-463-7547).

Scan this QR code with your smartphone to add your FINTEPLA CNE's phone number to your contacts.



Call anytime from 7:30 AM to 4:30 PM Central Time, Monday through Friday, and ask to talk with a Clinical Nurse Educator.



# Once you start FINTEPLA

ONWARD offers comprehensive support from day 1 to simplify your journey.

**Care Coordinators** are registered nurses trained in Dravet syndrome and treatment with FINTEPLA. Once enrolled in ONWARD, every family is given a dedicated Care Coordinator who will reach out and help you and your loved one start and stay on treatment.

#### Your Care Coordinator will:

- Review insurance coverage with you, keep you informed of your approval status, and offer options
- Explain what to expect, provide guidance with treatment reminders, and help find echocardiogram locations near you
- Connect with a specialty pharmacy to get your loved one's treatment
- Work with you and your healthcare provider to create a personalized plan that keeps your loved one on track

Once enrolled, you can call your Care Coordinator 7 AM to 7 PM Central Time, Monday through Friday, at 1-888-964-3649.

## Financial support for FINTEPLA

UCB is dedicated to making FINTEPLA available and affordable for every eligible patient.

 $ONWARD is provided as a service of UCB and is intended to support the appropriate use of UCB medicines. \\ONWARD may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.$ 

Visit Fintepla.com to learn more about available financial support programs.





# What's next for your loved one's treatment plan?

In this brochure, you've discovered how FINTEPLA can make a difference. You've taken some time to think about what those differences could mean for you, your loved one, and your family. You've identified what's most important to you when it comes to your loved one's treatment.

Now that you have the information and motivation you need, you're ready to take the next step. You're ready to talk about what's possible with FINTEPLA.

When you make an appointment to talk with your loved one's healthcare provider, you can use the notes you've taken in this brochure—about your loved one's needs and your goals—to guide your conversation.

Talk with your loved one's healthcare provider about FINTEPLA.

You can also contact a Clinical Nurse Educator at 1-833-GO-DS-LGS (1-833-463-7547).



## Important Safety Information (continued)

**5. Do not stop taking FINTEPLA without first talking to your healthcare provider.** Stopping a seizure medicine such as FINTEPLA can suddenly cause you to have seizures more often or seizures that do not stop (status epilepticus).

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.





Notes	





Notes	

#### **Indication**



- FINTEPLA is a prescription medicine used to treat seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older.
- It is not known if FINTEPLA is safe and effective in children less than 2 years of age.

#### **Important Safety Information**

#### FINTEPLA can cause serious side effects, including:

1. Problems with the valves in the heart (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension) have been associated with fenfluramine, the active ingredient in FINTEPLA. Your healthcare provider will do a test called an echocardiogram to check your heart and to evaluate for high blood pressure in the arteries of the lungs before you start taking FINTEPLA, again every 6 months during treatment, and one time 3 to 6 months after you take your last dose of FINTEPLA.

# Call your healthcare provider right away if you develop any of these signs and symptoms of heart or lung problems during treatment with FINTEPLA:

- · shortness of breath
- tiredness or weakness, especially with increased activity
- lightheadedness or fainting
- swollen ankles or feet
- chest pain

- sensations of a rapid, fluttering heartbeat (palpitations)
- irregular pulse
- bluish color of your lips and skin (cyanosis)

Because of the risk of heart valve problems (valvular heart disease) and high blood pressure in arteries of lungs (pulmonary arterial hypertension), FINTEPLA is only available through a restricted program called the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program. Before you or your child receives FINTEPLA, your healthcare provider or pharmacist will make sure you understand how to take FINTEPLA safely. If you have any questions about FINTEPLA, ask your healthcare provider, visit <a href="www.FinteplaREMS.com">www.FinteplaREMS.com</a>, or call 1-877-964-3649.

- Decreased appetite and decreased weight. Decreased appetite and decreased weight are both serious and common side effects of FINTEPLA in people with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS).
  - Your weight should be checked regularly during your treatment with FINTEPLA.
  - Your healthcare provider may need to make changes to your FINTEPLA dose if your weight decreases. In some cases, FINTEPLA may need to be stopped.
- 3. Sleepiness, sedation, and lack of energy (lethargy). These are both serious and common side effects of FINTEPLA in people with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS). Taking FINTEPLA with central nervous system (CNS) depressants, including alcohol, may increase sleepiness. Do not drive, operate heavy machinery, or do other dangerous activities until you know how FINTEPLA affects you.

#### Important Safety Information (continued)



**4.** Like all other antiepileptic drugs, FINTEPLA may cause suicidal thoughts or actions in a very small number of people (about 1 in 500).

# Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- trouble sleeping (insomnia)
- attempts to commit suicide
- new or worse irritability
- new or worse depression
- acting aggressive, being angry or violent
- new or worse anxiety
- acting on dangerous impulses
- feeling agitated or restless
- an extreme increase in activity and talking (mania)
- panic attacks
- other unusual changes in behavior or mood

#### How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

5. Do not stop taking FINTEPLA without first talking to your healthcare provider. Stopping a seizure medicine such as FINTEPLA can suddenly cause you to have seizures more often or seizures that do not stop (status epilepticus).

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

#### Do not take FINTEPLA if you:

- are allergic to fenfluramine or any of the ingredients in FINTEPLA. See below for a complete list of ingredients in FINTEPLA.
- are taking or have stopped taking medicines called monoamine oxidase inhibitors (MAOIs) in the last 14 days. This may cause a serious or life-threatening problem called **serotonin syndrome**. If you are not sure whether or not you are taking one of these medicines, contact your healthcare provider.

# Before taking FINTEPLA, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have or have had weight loss



- have or have had depression, mood problems, or suicidal thoughts or behavior
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. Tell your healthcare provider right away if you become pregnant while taking FINTEPLA. You and your healthcare provider will decide if you should take FINTEPLA while you are pregnant.
  - If you become pregnant while taking FINTEPLA, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling <u>1-888-233-2334</u> or go to <u>www.aedpregnancyregistry.org</u>. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if FINTEPLA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking FINTEPLA.

**Tell your healthcare provider about all the medicines you take,** including prescription and overthe-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

#### How should I take FINTEPLA?

- Read the Instructions for Use for information on the right way to use FINTEPLA.
- Take FINTEPLA exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much FINTEPLA to take and when to take it.
- FINTEPLA may be taken with or without food.
- Measure your dose of FINTEPLA using the dosing syringe that is provided by the pharmacy.
   Do not use a household teaspoon or tablespoon.
- FINTEPLA can be given through gastric and nasogastric feeding tubes.

#### What should I avoid while taking FINTEPLA?

• **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how FINTEPLA affects you. FINTEPLA may cause you to feel sleepy.

#### What are the possible side effects of FINTEPLA?

#### FINTEPLA may cause serious side effects, including:

- See "FINTEPLA can cause serious side effects" above
  - Serotonin syndrome. Serotonin syndrome is a life-threatening problem that can happen
    in people taking FINTEPLA, especially if FINTEPLA is taken with certain other medicines
    including: anti-depressant medicines called SSRIs, SNRIs, TCAs, and MAOIs; tryptophan;
    lithium; antipsychotics; St. John's Wort; dextromethorphan; tramadol.

## Important Safety Information (continued)



Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:

- mental status changes such as seeing things that are not there (hallucinations), agitation, or coma
- changes in blood pressure
- tight muscles

- fast heartbeat
- nausea, vomiting, diarrhea
- high body temperature
- trouble walking
- High blood pressure (hypertension). Hypertension is both a serious and common side
  effect. FINTEPLA can cause your blood pressure to increase even if you have never had high
  blood pressure before. Your healthcare provider will check your blood pressure while you are
  taking FINTEPLA.
- Increased pressure in your eyes (glaucoma). Symptoms of glaucoma may include:
  - red eyes
  - seeing halos or bright colors around lights
  - nausea or vomiting

- decreased vision
- eye pain or discomfort
- blurred vision

If you have any of these symptoms, call your healthcare provider right away.

- The most common side effects of FINTEPLA when used to treat Dravet syndrome (DS) include:
  - decreased appetite
  - diarrhea
  - low energy
  - respiratory infection
  - decreased weight
  - fever
  - constipation
  - abnormal echocardiogram
  - sleepiness

- problems with movement, balance, and walking
- increased drooling
- increased blood pressure
- vomiting
- falls
- seizures that do not stop
- weakness
- The most common side effects of FINTEPLA when used to treat Lennox-Gastaut syndrome (LGS) include:
  - diarrhea

sleepiness

tiredness

decreased appetite

vomiting

These are not all the possible side effects of FINTEPLA. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.



#### Keep FINTEPLA and all medicines out of the reach of children.

#### General information about the safe and effective use of FINTEPLA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FINTEPLA for a condition for which it was not prescribed. Do not give FINTEPLA to other people, even if they have the same symptoms that you have. It may harm them.

#### What are the ingredients in FINTEPLA?

Active ingredient: fenfluramine hydrochloride

**Inactive ingredients:** cherry flavor, citric acid, ethylparaben, hydroxyethylcellulose, methylparaben, potassium citrate, sucralose, and water.

FINTEPLA contains no ingredient made from gluten-containing grain (wheat, barley, or rye) and contains not more than 0.1% of carbohydrates, which is from the cherry flavoring.

Please see full <u>Prescribing Information</u>, including <u>Medication Guide</u>, for additional Important Safety Information on FINTEPLA.



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Visit <u>Fintepla.com</u> for more information and check out the FINTEPLA Facebook page for ongoing updates.



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## **Select Important Safety Information**

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