Getting started on Bylvay®

(odevixibat)

A guide for you and your loved ones.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store.

Side effects should also be reported to Ipsen via email at pharmacovigilance.uk-ie@ipsen.com or phone on 01753 627777. By reporting side effects, you can help provide more information on the safety of this medicine.

This leaflet is intended for patients with PFIC who have been prescribed Bylvay by a healthcare professional, their parents or other caregivers.

This guide is not intended to replace the leaflet in the medicine box which contains additional important information about the product and which you should read carefully.

This brochure was commissioned by Ipsen and has been developed with input from liver specialists.

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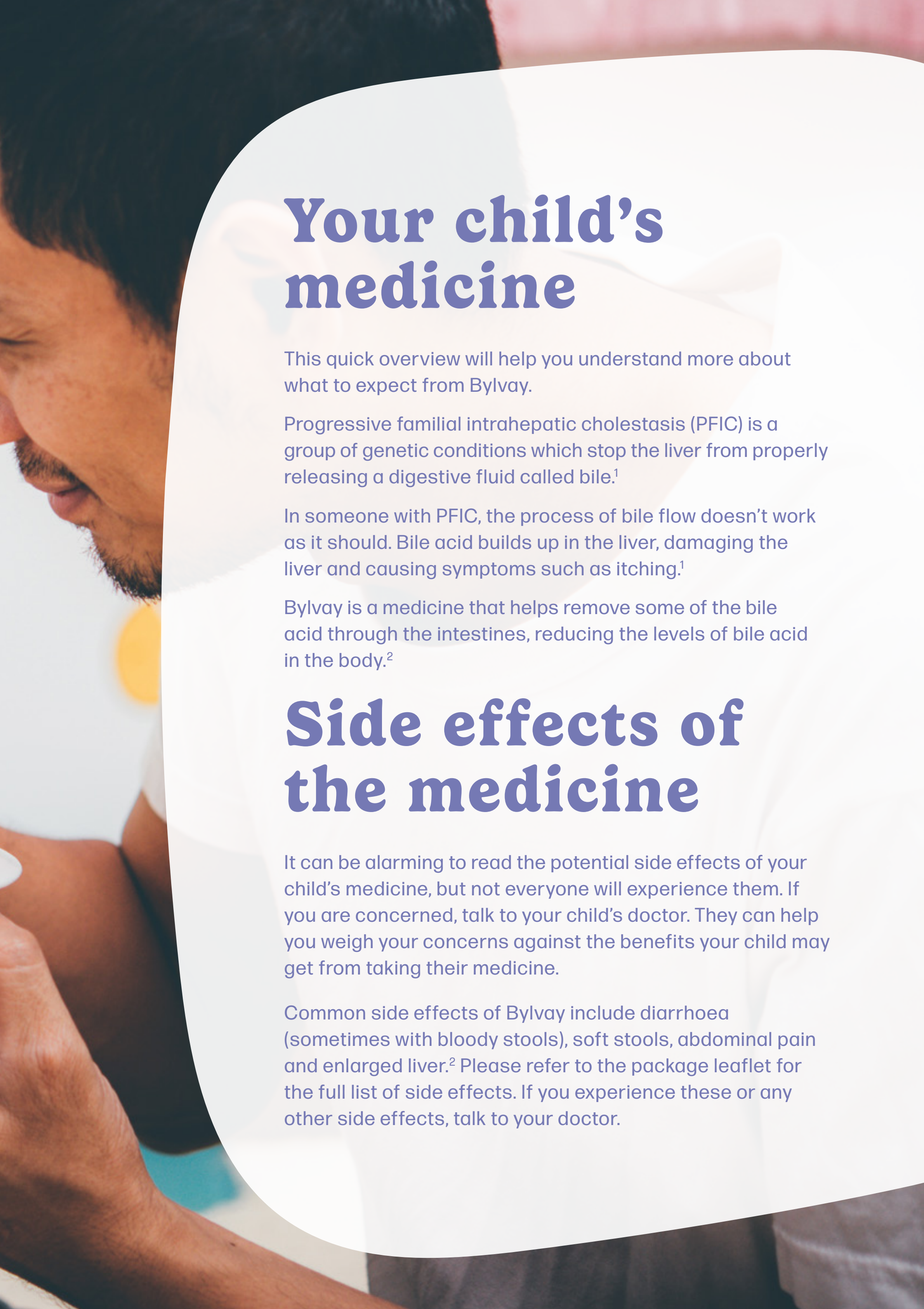

Your child's medicine

This quick overview will help you understand more about what to expect from Bylvay.

Progressive familial intrahepatic cholestasis (PFIC) is a group of genetic conditions which stop the liver from properly releasing a digestive fluid called bile.[1]

In someone with PFIC, the process of bile flow doesn't work as it should. Bile acid builds up in the liver, damaging the liver and causing symptoms such as itching.[1]

Bylvay is a medicine that helps remove some of the bile acid through the intestines, reducing the levels of bile acid in the body.[2]

Side effects of the medicine

It can be alarming to read the potential side effects of your child's medicine, but not everyone will experience them. If you are concerned, talk to your child's doctor. They can help you weigh your concerns against the benefits your child may get from taking their medicine.

Common side effects of Bylvay include diarrhoea (sometimes with bloody stools), soft stools, abdominal pain and enlarged liver.[2] Please refer to the package leaflet for the full list of side effects. If you experience these or any other side effects, talk to your doctor.

How to give your child their medicine[2]

Your child should take their medicine every morning, with or without food. If you forget in the morning, your child can take their Bylvay dose as soon as you remember, but they **must not** take more than one dose of Bylvay a day.

The dose of Bylvay is based on your child's weight. Your doctor will work out the right number and strength of capsules for your child to take.

Bylvay is taken as a capsule that can be swallowed whole with a glass of water or opened and sprinkled on food.

If your child is taking their medicine by opening the capsule to sprinkle on food:

1. At breakfast time, put a small amount (approximately 30 ml) of soft food in a bowl. Yoghurt, apple sauce, porridge, banana or carrot puree, or chocolate pudding or rice pudding are ideal.
2. Food should be at or below room temperature.
3. Hold the capsule horizontally at both ends over your child's food. Twist the ends in opposite directions.
4. Pull the capsule apart and empty the contents into the bowl. Tap the capsule so that all of the pellets come out. The capsule will split easily and the pellets will fall out onto the food.
5. Repeat steps 3 and 4 with the number of capsules you need for the right dose.
6. Gently mix the pellets in with the food.
7. Give your child the mixture straight away. Do not store it.
8. Ensure the whole dose is taken.
9. Give your child a drink of water.
10. Throw away the capsule cases.

Do[2]

- Give your child their medicine each day.
- Give your child their medicine as soon as you've prepared it.
- Check with your child's doctor if you have any concerns or questions.

Do not[2]

- Stop your child's medicine without talking to their doctor.
- Give your child a different dose than the one their doctor has prescribed.

Tips for remembering your child's medication

Build a routine

Your child needs to take their medicine at the same time every morning. It can help to get into a routine, so that this becomes a habit that you do automatically without thinking, like brushing your teeth.

Use reminder notes

Stick reminder notes somewhere you will see them, such as on the fridge.

Set an alarm

Set an alarm on your phone as a reminder. You can also download medicine reminder apps on your phone.

Make a plan

Link giving your child's medicine to something you already do in the morning. For example, 'I will make breakfast, then I will help my child take their medicine'.

Repeat

To build a habit, you need to repeat it. If giving your child their medicine feels like an effort now, remember that in a few weeks you probably won't have to think about it.

Support for your family

Having a child with a medical condition can be challenging for the whole family, but knowing who you can call on for support is helpful.

The support you need may be practical, emotional, or both, and you might find your needs change with time. You may not feel you need support–that's ok too.

Your extended family, friends and wider communities may be your sources of support. Organisations such as charities or hospital-based support groups may also be able to help.

Remember that some people may help without you needing to ask, while others might need guidance from you on how they can support your family. Either way, it's likely that people want to help you, and helping others through their challenges can be mutual too.

Having a child with a rare condition like PFIC can be isolating.
That's why it's so important to connect with other families.

Look for support groups on social media, or visit the website below:

childliverdisease.org

The information in this brochure has come from the following sources:

1. Children's Liver Disease Foundation. Progressive Familial Intrahepatic Cholestasis [online]. Available from: https://childliverdisease.org/liver-information/childhood-liver-conditions/progressive-familial-intrahepatic-cholestasis/ [Last accessed: October 2024].
2. Bylvay. Package leaflet: information for the patient. Ipsen 2024.

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