



Queensland
Government

Magnetic Resonance Imaging (MRI) Scan of Liver with Primovist® Consent

Child/Young Person (under 18 years)

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

A. Does the patient have capacity to provide consent?

- Yes Although the patient is a child/young person, the patient may be capable of giving informed consent and having sufficient maturity, understanding and intelligence to enable them to fully understand the nature, consequences and risks of the proposed procedure and the consequences of non-treatment – ‘Gillick competence’ (*Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112)
→ **GO TO section B**
- No Parent/legal guardian/other person* with parental rights and responsibilities to provide consent and complete this form
→ **COMPLETE section A**

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health ‘Guide to Informed Decision-making in Health Care’ and local policy and procedures. Complete the source of decision-making authority as applicable below.

If applicable, source of decision-making authority (*tick one*):

- Court order → Court order verified
 Legal guardian → Documentation verified
 Other person → Documentation verified

Name of parent/legal guardian/other person:

Relationship to child/young person:

B. Is an interpreter required?

- Yes No

If yes, the interpreter has:

- provided a sight translation of the informed consent form in person
 translated the informed consent form over the telephone

It is acknowledged that a verbal translation is usually a summary of the text on the form, rather than word-by-word translation.

Name of interpreter:

Interpreter code:

Language:

C. Patient/parent/legal guardian/other person confirms the following procedure(s)

I confirm that the referring doctor/clinician has explained that I have been referred for the following procedure:

Magnetic Resonance Imaging (MRI) scan of liver with Primovist®: Yes No

Name of referring doctor/clinician:

D. Risks specific to the patient in having a Magnetic Resonance Imaging (MRI) scan of liver with Primovist®

(Doctor/clinician to document additional risks not included in the patient information sheet):

E. Risks specific to the patient in *not* having a Magnetic Resonance Imaging (MRI) scan of liver with Primovist®

(Doctor/clinician to document specific risks in not having a Magnetic Resonance Imaging [MRI] scan of liver with Primovist® [disodium gadoxetate]):

F. Alternative procedure options

(Doctor/clinician to document alternative procedure not included in the patient information sheet):

DO NOT WRITE IN THIS BINDING MARGIN

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SW9544

MRI OF LIVER WITH PRIMOVIST® CONSENT



Magnetic Resonance Imaging (MRI) Scan of Liver with Primovist® Consent

Child/Young Person (under 18 years)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: [] M [] F [] I

G. Information for the doctor/clinician

The information in this consent form is not intended to be a substitute for direct communication between the doctor/clinician and the patient/parent/legal guardian/other person.

I have explained to the patient/parent/legal guardian/other person the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

[]

Designation:

[]

Signature:

Date:

[]

[]

H. Patient/parent/legal guardian/other person consent

I acknowledge that the doctor/clinician has explained:

- the 'Magnetic Resonance Imaging (MRI) Scan of Liver with Primovist®' patient information sheet
• my/the child's medical condition and proposed treatment, including the possibility of additional treatment
• the specific risks and benefits of the procedure
• the prognosis, and risks of not having the procedure
• alternative procedure options
• that there is no guarantee the procedure will improve the medical condition
• that if an immediate life-threatening event happens during the procedure, health care will be provided in accordance with good clinical practice and in my/the child's best interests
• that a doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure; this may include a doctor/clinician undergoing further training under supervision
• that if the doctor/clinician wishes to record video, audio or images during the procedure where the recording is not required as part of the treatment (e.g. for training or research purposes), I/the child will be asked to sign a separate consent form. If I/the child choose not to consent, it will not adversely affect my/the child's access, outcome or rights to medical treatment in any way.

I was able to ask questions and raise concerns with the doctor/clinician.

I understand I have the right to change my mind regarding consent at any time, including after signing this form (this should be in consultation with the doctor/clinician).

I/parent/legal guardian/other person have received the following consent and patient information sheet(s):

- [] 'Magnetic Resonance Imaging (MRI) Scan of Liver with Primovist®'
[] 'About Your Child's Anaesthetic'

On the basis of the above statements,

1) I/parent/legal guardian/other person consent to having a Magnetic Resonance Imaging (MRI) scan of liver with Primovist®.

Name of patient/parent/legal guardian/other person:

[]

Signature:

Date:

[]

[]

- [] I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person for this procedure (not applicable if the child/young person is Gillick competent and signs this form).

2) Student examination/procedure for professional training purposes:

For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to patient/parent/legal guardian/other person consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/parent/legal guardian/other person consent to a clinical student(s) undergoing training to:

- observe examination(s)/procedure(s) [] Yes [] No
• assist with examination(s)/procedure(s) [] Yes [] No
• conduct examination(s)/procedure(s) [] Yes [] No

Magnetic Resonance Imaging (MRI) Scan of Liver with Primovist®

Child/Young Person (under 18 years) | Informed consent: patient information

A copy of this patient information sheet should be given to the patient or parent/legal guardian/ other person to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.

In this information sheet, the word 'you' means the patient unless a parent, legal guardian or other person is providing consent on behalf of the patient, in which case the word 'you' means the parent, legal guardian or other person when used in the context of the person providing consent to the procedure.

The safety and effectiveness of Primovist® have not yet been established in people under 18 years of age. The benefit of having Primovist® in children/young persons under 18 must be weighed against the risks. This can be discussed with your doctor/clinician.



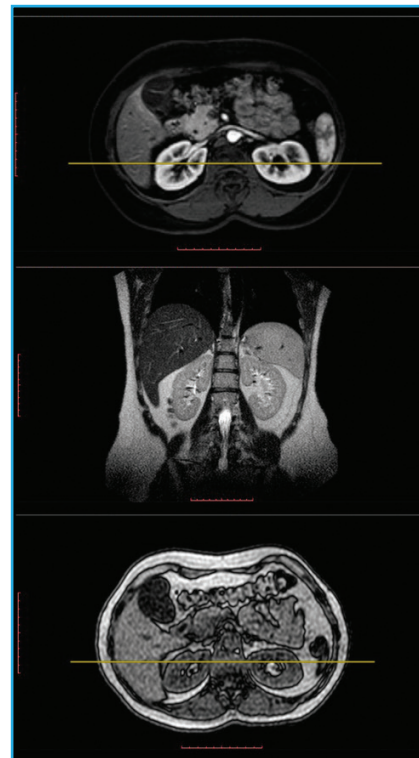
1. What is a Magnetic Resonance Imaging (MRI) scan of liver with Primovist® and how will it help me?

Primovist® (disodium gadoxetate) is a type of contrast that may be used during a Magnetic Resonance Imaging (MRI) scan of the liver. Primovist® is used to help detect and diagnose liver abnormalities and lesions that may not otherwise be seen by using MRI alone. It can also be used to show abnormalities in the biliary tree (the network of ducts and organs that produce, store, secrete and transport bile).

Primovist® is a colourless contrast that is injected into your blood stream. Primovist® is not a dye and it does not stain the inside of your body.

An MRI scan uses a strong magnetic field, radio waves and a computer to produce images of the body. MRI does not use any ionising radiation. For soft tissues, MRI images are generally more detailed than x-rays and other scans.

*Image: An abdomen MRI (adapted).
ID: 1268774644. www.shutterstock.com*



Preparing for the procedure

The Medical Imaging department will give you instructions on how to prepare for your procedure. It is important to follow the instructions that are given to you. Your procedure might be delayed if you don't follow all the preparation steps.

You are required to fast (stop eating and drinking) prior to the procedure. You will be given instructions when to have your last meal and drink.

Please tell the doctor/clinician if you are breastfeeding or pregnant, or suspect that you may be pregnant.

If the radiologist (doctor) thinks it would be useful to give you Primovist® for your MRI liver scan, you will be asked some questions to make sure it is safe for you to be given Primovist®.

MRI safety

- No one is permitted into the scanning room until they have answered a series of safety questions and taken off all removable metal objects from their body (e.g. jewellery, piercings, glasses and mobile phones). Your removable metal objects and personal items must be left outside the MRI scan room. You will be allocated a place to store your belongings safely.
- You will be required to change into a gown.
- It is important you answer the safety questions as correctly as possible to avoid injury.
- If you have an implant, foreign body (e.g. shrapnel) or inserted medical device, MRI staff will work to determine if it is safe for you to go into the strong magnetic field of an MRI scanner.
 - If you have an implant, foreign body or device that is not safe to go into an MRI scanner, you may not be able to have an MRI scan.
 - If you have an implant or device that is safe to enter a strong magnetic field under certain conditions, MRI staff will determine if your device or implant is safe to go into the MRI scanner at this hospital.
 - For some devices and implants, it may not be possible to have an MRI scan at one hospital, while it is possible at another hospital. This is because the strength of the magnetic field is not the same for all MRI scanners. The MRI scanner at one hospital might be able to meet the special conditions of your implant or device, whereas the MRI scanner at another hospital cannot.
- MRI safety also depends on the risk versus benefit for each individual; no one will be refused an MRI without a thorough review.

Some people find that being inside the light-filled, open-ended tunnel of the MRI machine makes them feel uncomfortable. If you feel uncomfortable, let the staff know as there are many ways that they can help you.

For a child/young person that is unable to lie still for their scan, a general anaesthetic may be required. Sedation or a general anaesthetic would need to be organised prior to the date of your scan.

Please contact the Medical Imaging department to discuss. If you are booked for an anaesthetic, please read the information sheet *About Your Child's Anaesthetic (for child/ young person)*. If you do not have one of these information sheets, please ask for one.

For a parent/legal guardian/other person of a patient having an MRI scan of liver with Primovist®

To prepare the patient for this procedure and to ease their concerns, tell them what they can expect to happen during the procedure. This information sheet will assist you with this.

We welcome your help and support in preparing the patient for the procedure and in explaining why it's so important to lie still.

At the discretion of the procedure staff:

- a parent/adult (unless pregnant) may be invited into the procedure room to support the patient. MRI staff will need to determine that this support person does not have an implant, foreign object or device that is not safe to go into an MRI scan room.
- if the patient is having a general anaesthetic you may be able to see them off to sleep. Once they are asleep you will be asked to leave the procedure room and wait in the waiting area.

Other children are not allowed into the procedure room, and they must be supervised at all times by another parent/ adult.

During the procedure

If you are having contrast or an intravenous (I.V.) medication it will be administered via an I.V. cannula, a small plastic tube that will be inserted into your hand or arm.

The MRI scanner itself should not cause you any pain. You may feel some vibrations and a warm sensation during your MRI scan. The MRI scanner is usually very noisy. You may hear thumping and knocking sounds. You will be given headphones and possibly earplugs to protect your hearing from the noise. Occasionally, you may experience muscle twitching and tingling in your arms or legs. This is normal and is called Peripheral Nerve Stimulation (PNS). The effects are temporary and will stop soon after the scan is complete.

MRI staff will not be in the room during the scan, but they will be able to see you and talk to you in between taking the images. Before the scan starts, you will be given a call button for you to press if there is an urgent concern.

Many images will be taken during the MRI scan, you need to keep still so the images are not blurry. You will be required to hold your breath, multiple times, for up to 20 seconds.

The Primovist® will be given through your I.V. cannula during the scan. While the Primovist® is being given it may cause shortness of breath. If this happens, it will go away quickly. It is important to follow all breathing instructions despite this feeling.

The scan and all the images usually take from 30–45 minutes.

When your scan is finished, your cannula will be removed if it is no longer required.



2. What are the risks?

In recommending the procedure, the doctor/clinician believes that the benefits to you from having the procedure exceed the risks involved. There are risks and possible complications associated with the procedure which can occur with all patients – these are set out below. There may also be additional risks and possible complications specific to your condition and circumstances which the doctor/clinician will discuss with you. If you have any further concerns, please ensure that you raise them with the doctor/clinician prior to giving consent to the procedure.

Common risks and complications of the procedure

- minor pain, bruising and/or infection from the I.V. cannula. This may require treatment
- some diseases and medicines, including complementary medicines, have the ability to affect blood clotting. A list of commonly affected medicines is found here www.health.qld.gov.au/consent/bloodthinner.

Uncommon risk and complications of the procedure

- the scan may not be possible due to medical and/or technical reasons
- contrast or medication injected into a blood vessel may leak outside the blood vessel, under the skin and into the tissue. This may require treatment. In very rare cases if the skin breaks down, surgery may be required.

Rare risks and complications of the procedure

- thermal burns are extremely rare due to precautionary measures taken by MRI staff
- injury, severe injury or death because of an undeclared metal implant or if an implant is scanned without the necessary conditions for safety
- death because of an MRI scan is extremely rare.

Common risks and complications of Primovist®

- headache/nausea
- disodium gadoxetate (Primovist®) is a gadolinium-based contrast agent. Small amounts of gadolinium may remain in tissues of the body, including the liver, bone and brain. This is called gadolinium retention and its effects on the body are an area of ongoing research.

Uncommon risks and complications of Primovist®

- chest pain
- vomiting
- dizziness
- bad taste in your mouth
- shortness of breath/difficulty breathing
- increased blood pressure/flushing (redness and warmth on your skin due to increased blood flow)
- sensation of pins and needles
- back pain.

Rare risks and complications of Primovist®

- allergic reactions rarely occur, but when they do, they usually occur within the first 30 minutes, however there can be delayed reactions hours to days after. If you notice any of the reactions below, seek medical attention straight away. The reactions vary from:
 - mild: headache, brief nausea, dizziness, hives, rash and itching
 - moderate: widespread hives, headache, facial swelling, vomiting, shortness of breath
 - severe: severe reactions are rare but include life-threatening heart palpitations, very low blood pressure, throat swelling, seizures and/or cardiac arrest, anaphylactoid shock (non-immune related allergy)
- Nephrogenic Systemic Fibrosis (NSF) can occur to those who have severe renal impairment and are given Primovist®. Please refer to the sections '*Precautions*' and '*Kidney function*' below to learn more about NSF
- heart palpitations/faster heartbeat which may require medication and/or further treatment
- measles-like rash, excessive sweating
- discomfort, generally feeling unwell.

Precautions

Primovist® cannot be given to some people. If the radiologist (doctor) thinks it would be useful to give you Primovist® for your MRI scan, you will be asked some safety questions to see if there are any reasons that you should not be Primovist®. If it is not safe for you to be given Primovist®, the radiologist may decide to do an MRI scan without Primovist® or do a different test.

Kidney function

Primovist® is removed from the blood by the kidneys and liver. It is easily removed from the body of people who have normal kidney and liver function.

You may need to have a blood test to find out the level of your kidney and liver function before you are given Primovist®.

Nephrogenic Systemic Fibrosis (NSF) is an extremely rare condition that results in scarring or thickening of the skin and tissues throughout the body. It can occur days to years following exposure to gadolinium. It is severely disabling and often fatal. As NSF has almost only ever been seen in people with severely reduced kidney function and those on dialysis, every effort is made to avoid giving gadolinium to these patients. However, sometimes there is no good alternative and contrast is required to help rapidly and effectively diagnose serious organ and life-threatening diseases so effective treatment can be started. It is reasonable for almost all patients with kidney disease and those on dialysis to receive contrast in these circumstances.

Pregnancy and breastfeeding

Primovist® should not be given to a pregnant or breastfeeding person unless it is considered absolutely necessary. You can discuss this with the doctor/clinician.

If Primovist® is given while you are breastfeeding, please discuss with your doctor if it's recommended to stop breastfeeding for 24 hours after you have been given Primovist®.

What are the risks of not having an MRI scan of liver with Primovist®?

There may be adverse consequences for your health if you choose not to have the proposed procedure. Please discuss these with the referring doctor/clinician.

If you choose not to have the procedure, you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the procedure. Please contact the doctor/clinician to discuss.



3. Are there alternatives?

Making the decision to have a procedure requires you to understand the options available. Please discuss any alternative procedure options with your doctor/clinician before signing the consent form.



4. What should I expect after the procedure?

Your healthcare team will talk to you about what to expect after your procedure and upon discharge from hospital.

Primovist® does not impact your ability to carry out normal activities and you should be able to continue with your day as normal.

Remind any doctor/clinician, dentist or pharmacist you visit that you have been given Primovist®.

If you are to have any blood tests, tell your doctor/clinician you have received Primovist®. Primovist® may alter the results of iron and bilirubin levels detected in a blood test for 1 to 4 days after your scan.

You will receive the results of the examination from your treating team at your next follow-up appointment. Please make an appointment if you do not already have one.



5. Who will be performing the procedure?

Radiographers, doctors, nuclear medicine technologists, sonographers, nurses, and medical imaging assistants make up the medical imaging team. All or some of these professionals may be involved in your procedure.

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure. This could include a doctor/clinician undergoing further training, however all trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/clinician will be performing the procedure, please discuss this with the doctor/clinician.

For the purpose of undertaking professional training in this teaching hospital, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to your consent, assist with/conduct an examination or procedure on you.

You are under no obligation to consent to an examination(s) or a procedure(s) being undertaken by a clinical student(s) for training purposes. If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way.

For more information on student care, please visit www.health.qld.gov.au/consent/students.



6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website www.qld.gov.au/health/services/hospital-care/before-after where you can read about your healthcare rights.

You can also see a list of blood thinning medications at www.health.qld.gov.au/consent/bloodthinner.

Further information about informed consent can be found on the Informed Consent website www.health.qld.gov.au/consent. Additional statewide consent forms and patient information sheets are also available here.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss this with your doctor/clinician.

Queensland Health recognises that First Nations People's culture must be considered in the patient's clinical care to ensure their holistic health and individual needs are met.

7. Questions

Please ask the doctor/clinician if you do not understand any aspect of this patient information sheet or if you have any questions about your proposed procedure.

If you have further questions prior to your appointment, please contact the Medical Imaging department via the main switchboard of the facility where your procedure is booked.

8. Contact us

In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.