

MENTAL HEALTH & ADDICTIONS PROGRAM PROCEDURE

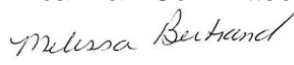
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ISSUE DATE: December 1, 2021

TITLE: **SUBLOCADE ADMINISTRATION IN ADULT INPATIENTS – TO BE ADMINISTERED BY SPECIALLY TRAINED STAFF ONLY**

Page 1 of 13

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Approval: Melissa Bertrand Clinical P&P Committee 	Date: December 1, 2021

PURPOSE

The purpose of this document is to outline the procedure for obtaining and administering Sublocade (a non-formulary medication that is not supplied by HSN) to adult patients admitted to the hospital.

PROCEDURE

Equipment

- Ice pack (optional, but recommended for pain control)
- Alcohol Swab
- Sublocade administration kit (includes: medication, syringe, safety-engineered needle)
- Dressing or bandaid (if required)

Special Instructions (see appendix B for other special considerations)

- **To be given ONLY by specially trained staff from the Addictions Medicine Consult Service or staff from the Addictions Medicine Unit** (hereinafter referred to as administering nurse).
- When the medication is injected, it causes an exothermic reaction when it comes into contact with body fluid, forming a depot under the skin which will absorb over the span of a month (patient may experience intense burning at the time of injection – warn patient ahead of time to prepare them, and apply icepacks pre/post injection for pain management).
- To be given subcutaneously **ONLY**. IV or IM administration can cause necrosis or emboli.

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- Dosing considerations:
 - Patient needs to be stabilized on a dose of at least 8mg of Subxone daily for at least 7 days prior to administration.
 - Medication peaks 24 hours post 1st injection, and a steady state is achieved within 4-6 months.
 - Dosing starts at 300mg/month (1.5mL) x 2 months, then can be decreased to 100mg/month (0.5mL) as a maintenance dose (due to the larger volume injected, the 300mg doses are more painful) depending on patient's clinical picture
 - There is a minimum of 26 days between doses.
 - If patient is receiving a subsequent dose, the prior depot may not be fully absorbed by the time of administration. Patient may have several small depots remaining until all of the medication is absorbed – this should not delay the scheduled dose. If medication is discontinued, the patient should be monitored for several weeks to months for signs and symptoms of withdrawal.

Method

In preparation

1. Obtain Physician or Nurse Practitioner order for Sublocade (they need to have specialized certification to order Sublocade).
2. If this is a continuation of Sublocade treatment, patient's nurse to confirm the date of the last dosage with the patient's pharmacy or healthcare provider.
3. For treatment initiation, complete patient education on Sublocade to ensure patient understands contraindications and any potential risks associated with the medication (patient information pamphlet – Appendix A, physical copies can be obtained from the Addictions Medicine Unit and given to the patient to read prior to the medication being administered).
4. Process order for Sublocade and send through DocuScripts, and fax prescription to HSNRx (Appendix D).
5. Confirm order with HSNRx (expect up to a 24 hour turnaround on Monday-Friday orders, excluding holidays for medication delivery).
6. When the primary nurse is **ready** to have the medication administered (24 hours after order sent), they are to call HSNRx to confirm it is ready and let them know they are ready to have it delivered to the unit. *Note: The primary nurse should be available to receive the medication if the administering nurses is not yet on the floor, and should be prepared to sign documentation on delivery. Everything should be ready for the administering nurse to come administer the medication since it is a controlled substance that is now out of the fridge.*
7. Upon receiving the call from the primary nurse indicating they are ready for the medication to be delivered, HSNRx will have HSN pharmacy pick up the medication, and sign the manual controlled substance document and deliver it to the unit.
8. An e-req must be submitted to Pharmacy requesting the medication for tracking purposes.
9. The primary nurse will receive the medication from pharmacy and sign the manual controlled substance document on receipt.
 - A. Medications will be administered by a trained addictions nurse who has completed the SLP, has completed the quiz affiliated and has done a witnessed administration (Nurse Clinician from Addictions Medicine will witness).
 - B. Nurse from either the Addictions Medicine Unit or the Addictions Medicine Consult Service (AMCS) must be contacted to organize best time for medication administration if it is happening outside of the AMU.

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10. The receiving nurse (either the primary nurse or the administering nurse) and the delivering Pharmacy technician will sign the Delivery Signature Receipt and take a copy. Original will go with the Pharmacy Technician, and the copy will be placed in the chart in the medication section.
11. The nurse who accepted the medication will ensure it has been out of the fridge for 15 minutes prior to administration to allow it to get to room temperature. If the primary nurse is the one to receive the medication, they **MUST** keep it with them until such time as they can hand it over to the administering nurse as it is a controlled substance (do not place it back in the fridge).
12. The primary nurse and the administering nurse will sign for the medication in the STAT section of the CMAR or in the scheduled section of the CMAR next to Sublocade which will appear as a Patient's Own Medication.
13. The administering nurse will give the injection to the patient (as per administration steps below)
14. If this is a subsequent dose - confirm previous administration location with outpatient Pharmacy or by asking patient (i.e. right upper quadrant of abdomen generally used for all first doses) (Appendix B).
15. If the dose cannot be given to the patient for whatever reason (i.e. the patient has left or cannot be located), it needs to be sent back to pharmacy as it is not to be stored on the unit.

Administration (ONLY for trained Addictions Staff)

1. Remove items from package:
 - a. Check liquid clarity. It can range from colourless to amber in colour.
 - b. Look for any contaminants or particles. If any contaminants or particles please contact pharmacy for further instruction.
2. Prepare for injection:
 - a. Apply icepack to site for at least 2 minutes prior to injection (this is as per patient preference and not mandatory).
 - b. Attach safety needle (screw on clockwise).
 - c. Prepare the abdomen by choosing most appropriate site based on rotation schedule and cleanse with an alcohol swab. The site should be rotated monthly beginning with right upper quadrant (RUQ), then proceed through left upper quadrant (LUQ), left lower quadrant (LLQ) and right lower quadrant (RLQ) (Appendix B).
 - d. Remove excess air from the syringe. The medication is very viscous (it may take longer for the air bubbles to rise).
3. Inject the medication:
 - a. Pinch the site, and lift the skin to decrease the risk of injecting the medication into a muscle.
 - b. Inject the medication with a steady push. It may take longer to inject due to its viscosity.
 - c. Withdraw the needle. Approximately 0.1mL will remain in the needle. Do not rub the site post injection. Apply gauze if required.
 - d. Lock the needle. Dispose of needle and syringe in the sharps container.
 - e. Reapply icepack for 2-3 minutes to assist with pain control.
 - f. Monitor closely for respiratory depression and decreased level of consciousness for the first 60 minutes post administration then continue routine hourly checks as per hospital policy.
 - i. If patient is receiving a dose of Sublocade on an inpatient unit other than the Addictions Medicine Unit, patient must remain on the unit for 60 minutes post

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administration so the unit can monitor them. After the 60 minutes of enhanced observation, patient may leave floor as previous.

4. Patient instructions:
 - a. Instruct the patient that they will have a lump that will decrease in size over several weeks to months. This is normal.
 - b. Tell the patient not to rub the site, to avoid tight clothing or belts that cover the injection site.
 - c. If this is the first dose, advise the patient that they should not operate heavy equipment (i.e. vehicles), or anything that requires balance or focus for at least 24 hours after administration.
5. Document Administration:
 - a. Document time and date on the Sublocade tracking sheet – this will require a second staff signature and will allow you to chart location administered as well. This will be kept at the front of the Medication tab with the CMARs (appendix C).
 - b. Sign CMAR to indicate that the dose has been administered.
 - c. Send RFS to pharmacy indicating that the dose was given.
 - d. Pharmacy will update the CMAR and confirm that the date for the next dose is updated.

Definitions

1. Exothermic: a chemical reaction that releases energy as heat
2. Depot: a solid mass that is formed (occurs when the medication comes into contact with body fluids)

References and Related Documents

Invidior, Sublocade Certification Training - www.sublocadecertification.ca accessed May 2021

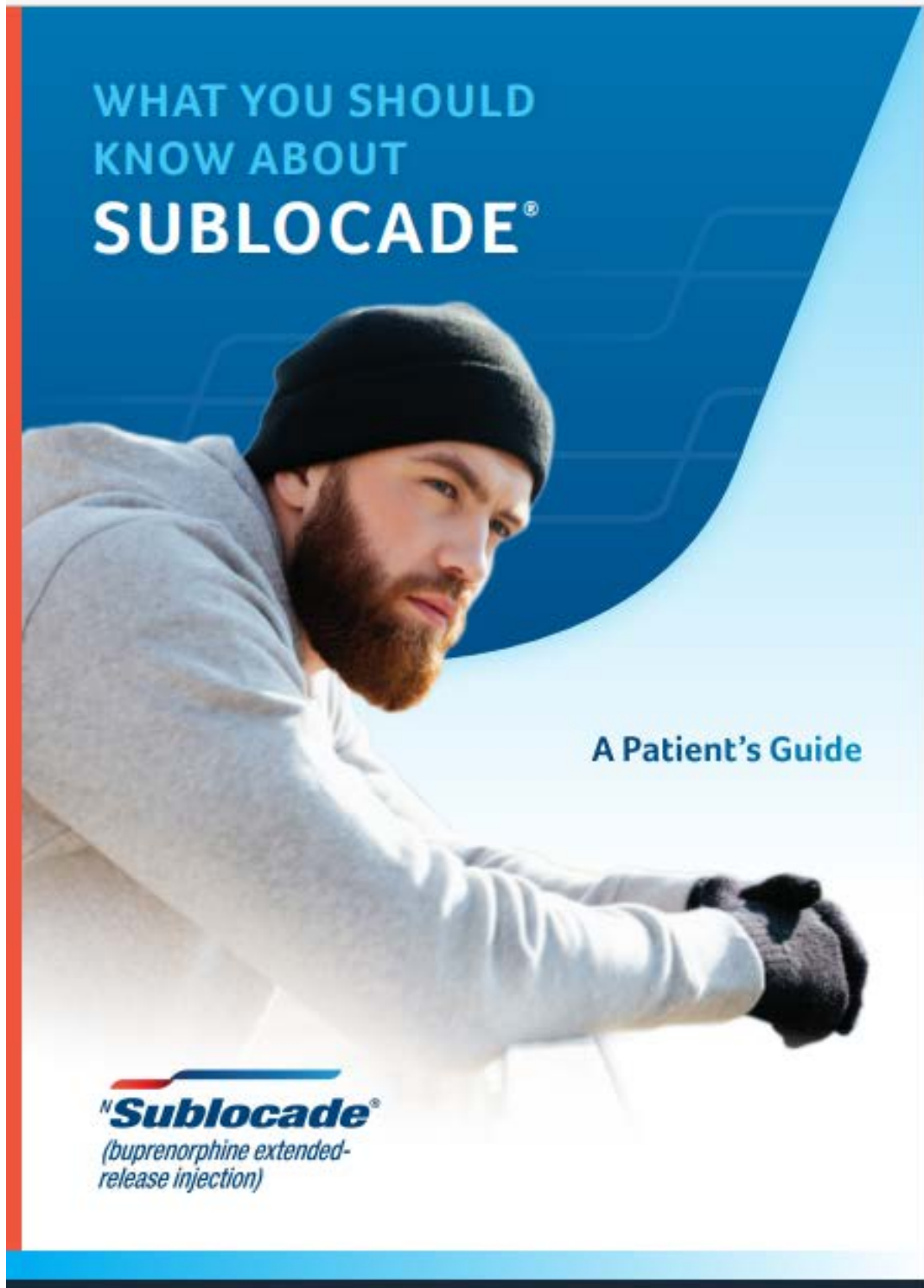
Invidior, What You Should Know About Sublocade: A Patient's Guide accessed May 2021

Joel Bordman MD, Robin Nocilla NP, Matthew Manz RPh. "A Live Virtual Sublocade Educational & Clinical Experiences Speaking Engagement" May 27, 2021, virtual session

Product Monograph: https://pdf.hres.ca/dpd_pm/00048406.PDF

APPENDICES

Appendix A



TITLE: SUBLOCADE ADMINISTRATION IN ADULT INPATIENTS

In this booklet, you will find...

Important information on the risks related to SUBLOCADE® and on what you'll need to know before, during and after starting treatment. We'll provide answers to key questions such as:

- What is SUBLOCADE® used for, and why am I taking it?
- What information will my doctor need from me?
- How is SUBLOCADE® given, and how often will I need to take it?
- What side effects might I expect while on treatment with SUBLOCADE®? And what should I do if I experience side effects?
- What happens when I stop treatment with SUBLOCADE®?

We hope you find this booklet helpful. If you have any questions that are not answered in this booklet, please feel free to ask your doctor.

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Understanding my treatment

WHAT IS SUBLOCADE® USED FOR?

SUBLOCADE® is used to treat adult patients who:

- have moderate to severe opioid use disorder,
- and are currently taking a transmucosal buprenorphine-containing product for at least 7 days.

SUBLOCADE® should be used along with counselling and psychosocial support.



WHAT IS SUBLOCADE®?

SUBLOCADE® contains a medicinal ingredient called buprenorphine. It is given by injection at your doctor's office.

HOW DOES SUBLOCADE® WORK?

SUBLOCADE® works in a similar way as other opioid drugs that are used in the treatment of pain. When you stop taking opioid drugs, you can experience withdrawal. SUBLOCADE® helps control the symptoms you feel when you are in withdrawal.

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Treatment with SUBLOCADE®


HOW IS SUBLOCADE® GIVEN?

After taking a transmucosal buprenorphine-containing treatment for a week or more, your doctor or nurse will inject a 'starting' dose of SUBLOCADE®.

- SUBLOCADE® is injected as a liquid just under the skin around the stomach area, forming a small lump (this is called a 'depot').
- The starting dose of SUBLOCADE® is 300 mg/1.5 mL. You would need to be on this dose for 2 months.
- This will be followed by a 'maintenance' dose of 100 mg/0.5 mL. Your doctor could adjust your dose if needed.

Remember, SUBLOCADE® should never be injected into a vein or a muscle. If injected into a vein it can cause serious harm or death.

If injected into a vein, SUBLOCADE® can cause serious harm or death.



WHAT DOES 'DEPOT' MEAN?

A depot looks and feels like a small bump under the skin where SUBLOCADE® is injected (called an 'injection site'). This bump will remain in the injection site for several weeks, getting smaller over time. Do NOT rub or massage the injection site. Try to avoid wearing any belts or waistbands that may irritate the skin around the injection site.

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HOW OFTEN WOULD I NEED TO RECEIVE SUBLOCADE®?

The starting dose will be given once a month for 2 months. This will be followed by a monthly injection, using a lower dose of SUBLOCADE®. This dose may be increased, if your doctor feels that it's needed.

SHOULD I TELL MY FAMILY THAT I'M RECEIVING SUBLOCADE®?


Yes. You should tell members of your family that you're using SUBLOCADE® to treat your opioid use disorder.

Before taking SUBLOCADE

WHAT SHOULD I TELL MY DOCTOR?

Talk to your healthcare professional about any health conditions or problems you may have before you receive SUBLOCADE®. Please see the product insert for more information.

Before starting SUBLOCADE®, don't forget to give your doctor a complete list of medicines you have been, or are now, taking. These include all 'natural' or herbal medicines as well as any vitamins and minerals.



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Possible side effects with SUBLOCADE®

WHAT KINDS OF SIDE EFFECTS CAN I EXPECT?

You might experience these side effects at the injection site: itching, pain, redness, bruising, or swelling.

Other side effects could include: drowsiness, insomnia, dizziness, fainting or feeling faint, feeling weak or tired, nausea, vomiting or poor appetite, dry mouth, headache, vision problems, itching, sweating, constipation, low sex drive, impotence (erectile dysfunction), infertility.

These are not all the possible side effects you may feel when taking SUBLOCADE®. If you experience any side effects not listed here, contact your healthcare professional.

Constipation can be a problem with SUBLOCADE®.
It is a good idea to ask your doctor or pharmacist about ways to prevent constipation.

ARE THERE ANY SERIOUS SIDE EFFECTS I SHOULD KNOW ABOUT?

Here's a list of possible side effects – and what you should do about them.

SERIOUS SIDE EFFECTS THAT SHOULD CAUSE YOU TO STOP TAKING SUBLOCADE® AND GET HELP RIGHT AWAY:

COMMON EFFECTS: Signs of an allergic reaction (rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing)

RARE EFFECTS: Signs of an overdose (hallucinations; confusion; inability to walk normally; slow or weak breathing; extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, cold and clammy skin); signs of respiratory depression: slow, shallow or weak breathing; signs of bowel blockage (impaction): abdominal pain, severe constipation,

nausea; signs of a serious condition called Serotonin Syndrome (agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea)

SERIOUS SIDE EFFECTS YOU SHOULD TELL YOUR DOCTOR ABOUT IN ALL CASES:

UNCOMMON EFFECTS: Dark urine, drop in blood pressure (dizziness, fainting, light-headedness) fainting, hallucination (seeing or hearing things that are not really there), jaundice (your skin or the white part of your eyes look yellow), light-coloured stools

RARE EFFECTS: withdrawal (nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating), fast, slow or irregular heartbeat (heart palpitations)

SERIOUS SIDE EFFECTS YOU SHOULD TELL YOUR DOCTOR ABOUT ONLY IF THEY ARE SEVERE:

COMMON EFFECTS: Itching, nausea, stomach pain

UNCOMMON EFFECTS: Loss of appetite

RARE EFFECTS: Signs of low blood pressure (dizziness, fainting, light-headedness)

For more information on side effects with SUBLOCADE®, please see the patient insert.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

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Serious warnings and precautions

SUBLOCADE® should not be used by women who are:

- Pregnant.
- Able to get pregnant but are not using an effective or reliable form of birth control.

Life-threatening breathing problems can happen while taking SUBLOCADE®, especially if not used as directed. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.

If you received SUBLOCADE® while pregnant, whether for a short or long time, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after they are born. Get help right away for your baby if you notice:

- Breathing changes (such as weak, difficult or fast breathing)
- Not feeding well
- Is unusually difficult to comfort
- Shaking (tremors)
- Stiffness
- Increased stools or diarrhea
- Sneezing, yawning, vomiting, or fever

SUBLOCADE® should not be used in women who are pregnant. Your doctor will decide whether the benefit of giving you SUBLOCADE® outweighs the risk to your unborn baby.

WHAT OTHER SERIOUS RISKS SHOULD I KNOW ABOUT?

SUBLOCADE® can cause an abnormal heart beat in some people. Doctors call this 'QTc Prolongation'. You need to tell your doctor or nurse if you have problems with your heart.

Even if you use SUBLOCADE® as prescribed, you are at risk for abuse and misuse. To understand your risk of abuse and misuse, you should speak to your doctor.

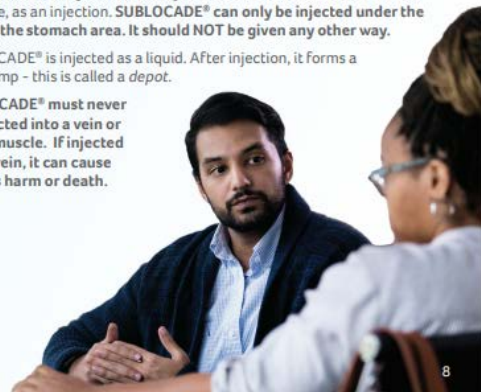
Your doctor should also monitor you to see if you develop these behaviours.

I DON'T LIKE INJECTIONS. CAN I RECEIVE SUBLOCADE® ANY OTHER WAY?

No. As mentioned, you should only receive SUBLOCADE® from a doctor or nurse, as an injection. SUBLOCADE® can only be injected under the skin of the stomach area. It should **NOT** be given any other way.

SUBLOCADE® is injected as a liquid. After injection, it forms a solid lump – this is called a *depot*.

SUBLOCADE® must never be injected into a vein or into a muscle. If injected into a vein, it can cause serious harm or death.



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Serious drug interactions

CAN I DRINK ALCOHOL OR TAKE OTHER DRUGS WITH SUBLOCADE®?

You should NOT drink alcohol or take central nervous system depressants while you're receiving SUBLOCADE®.

Taking the following medications while you are on SUBLOCADE® can cause severe drowsiness, decreased awareness, unusually slow or weak breathing, coma and death:

- other opioid medication (used to treat pain)
- benzodiazepines (used to treat anxiety or to help you sleep)
- alcohol (this includes prescription and non-prescription medications that contain alcohol)
- other central nervous system depressants, such as
 - » street drugs
 - » drugs used during surgery
 - » muscle relaxants
 - » drugs to treat depression
 - » drugs used to treat nausea and vomiting
 - » drugs used to treat serious mental or emotional disorders (such as schizophrenia)

Taking SUBLOCADE® in combination with the above drugs should be avoided as it may result in you feeling stronger effects from the drug than usual. This can possibly lead to an accidental overdose that can be fatal.

This is not a complete list. For more information on potential drug interactions with SUBLOCADE®, please see the patient insert.

You must let your doctor know if you are taking these or any other drugs.

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While on SUBLOCADE®

DOES SUBLOCADE® HAVE ANY EFFECT ON SEXUAL FUNCTIONING?

Using opioids like SUBLOCADE® for a long time could lead to a decrease in sex hormone levels. It may also lead to low libido, erectile dysfunction or being infertile.

WILL SUBLOCADE® AFFECT MY ABILITY TO DRIVE OR OPERATE MACHINERY?

SUBLOCADE® may make you may feel sleepy, dizzy or light-headed.

Before doing anything that needs special attention, you should wait until you know how you react to SUBLOCADE®.

These effects may happen more often in the first few days after your injection.

WHAT IF I'M EXPERIENCING SHORT-TERM PAIN?

If you have to take other medicines for short-term pain, you may not be able to get full pain relief from other opioids while on SUBLOCADE®. Tell the doctor who's treating you for pain that you are on SUBLOCADE®.

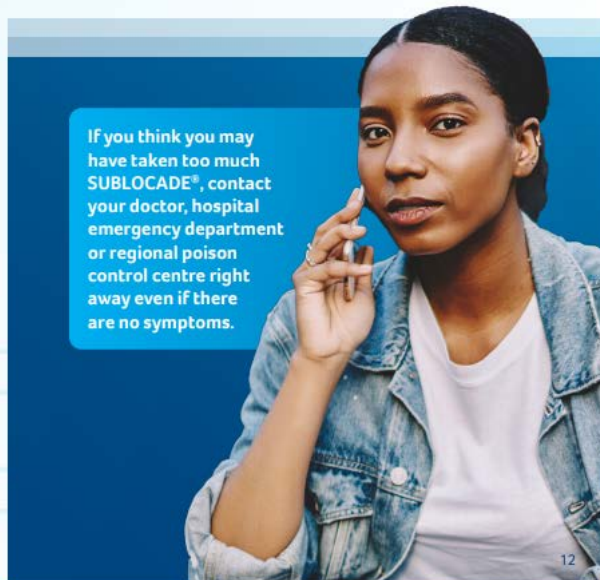
WHAT IF I MISS A DOSE?

If you miss a dose of SUBLOCADE®, see your doctor right away.

WHAT ARE THE SIGNS OF AN OVERDOSE?

Watch for any of these signs: unusually slow or weak breathing, dizziness, confusion, extreme drowsiness, blue or purple lips, slow heart rate, nausea and vomiting, and 'pinpoint pupils' (pupils that are abnormally small under normal lighting conditions).

If you think you may have taken too much SUBLOCADE®, contact your doctor, hospital emergency department or regional poison control centre right away even if there are no symptoms.



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If you think you may have taken too much SUBLOCADE®, contact your doctor, hospital emergency department or regional poison control centre right away even if there are no symptoms.

Where to look for help

FOR FURTHER INFORMATION AND/OR SUPPORT, SEE THE FOLLOWING RESOURCES:

- Centre for Addiction and Mental Health (CAMH): www.camh.ca
- Canadian Assembly of Narcotics Anonymous: www.canaaacna.org

Ask your healthcare provider to list any local resources in the space below.






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Appendix B

Figure 1

Steps for administering Sublocade



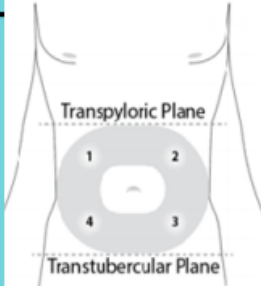
- ## 1 Remove items from package

Check liquid clarity. It can range from colourless to amber in colour. Look for any contaminants or particles.
- ## 2 Prepare for injection

 - Attach safety needle (screw on clockwise)
 - Prepare the abdomen. The site should be rotated monthly. Begin with RUQ, then proceed through LUQ, LLQ, and RLQ (see visual below).
 - Remove excess air from the syringe. The medication is very viscous (it may take longer for the air bubbles to rise).
- ## 3 Inject the medication

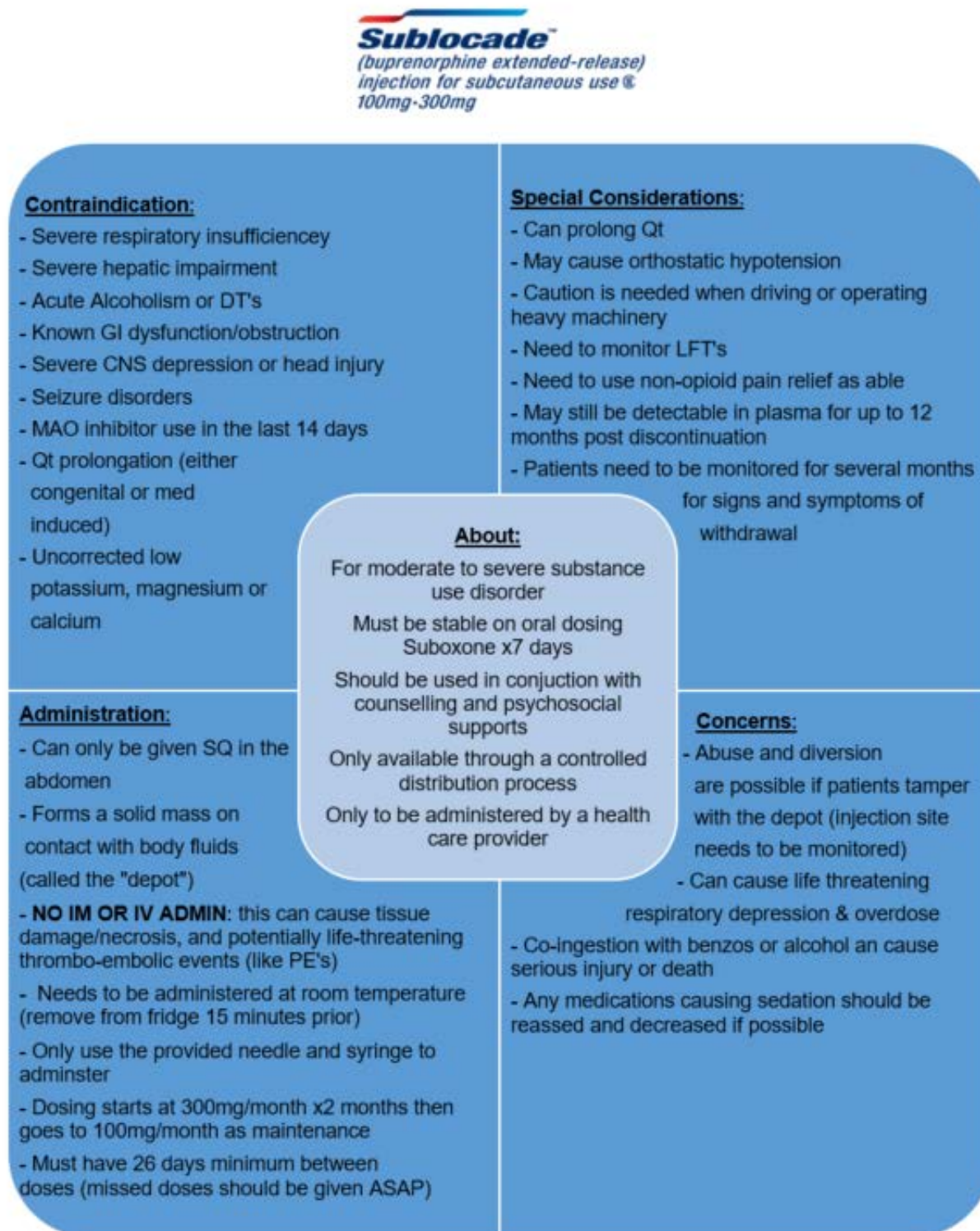
 - Pinch the site, and lift the skin to decrease the risk of injecting the medication into a muscle.
 - Inject the medication with a slow and steady push. It may take longer to inject due to its viscosity.
 - Withdraw the needle. Approximately 0.1mL will remain in the needle. Do not rub the site post injection. Apply bandage or gauze.
 - Lock the needle. Dispose of the needle and syringe in the sharps container.
- ## 4 Patient instructions

 - Instruct the patient that they will have a lump that will decrease in size over several weeks.
 - Tell the patient not to rub the site, and try to avoid tight clothing over the injection site.



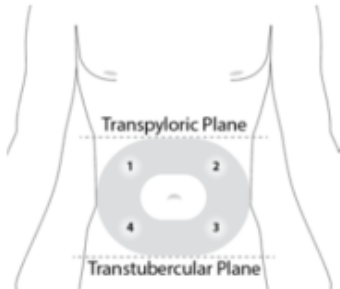
TITLE: SUBLOCADE ADMINISTRATION IN ADULT INPATIENTS

Figure 2



Appendix C

Health Sciences North/Horizon Santé Nord



Sublocade® Dosing & Administration Quick Facts¹

To be given monthly with at least 26 days apart.
To be given subQ in abdomen only, between the
transpyloric and transtuberular planes.
Unavoidable dosing delays of up to 2 weeks are not
expected to clinically impact treatment significantly.

[illegible]¹Indivior UK Limited. Sublocade® Product Monograph. Available at https://pdf.hres.ca/dpd_pm/00054686.PDF.

Appendix D**Tip Sheet: Getting Sublocade from HSNRx**

Sublocade is not on HSN's formulary, so it must be ordered from the outpatient pharmacy HSNRx.

HSNRx Contact Information

Phone Ext.	7349
Fax	(705) 523-7321
Hours of Operation	Mon. to Fri. 0800 – 1600

Once you have the order for Sublocade:

1. Scan the order into the DocuScript system.
2. Create an **outpatient prescription**. Make sure the prescription includes:
 - The script that should read:

Sublocade _____ mg SubQ x 1

- Patient's **full name**
 - Patient's **date of birth**
 - Patient's **health card number**
 - Patient's **address**, including **postal code**
 - Patient's **phone number**
 - Patient's **allergies**
 - Patient's **home pharmacy name and phone number**, if available
 - Physician **CPSO number**
 - An **extension**, for HSNRx to call in case of need
3. **Fax** the prescription to HSNRx at (705) 523-7321.
 4. Once the Sublocade dose is administered, **enter RFS to Pharmacy for the time the next dose is due**.

Note

Sublocade prescribing is restricted to physicians who are registered Sublocade prescribers.