

treatment. Talk to your pharmacist or healthcare provider about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking OTFC.

OTFC contains sugar. Cavities and tooth decay can happen in people taking OTFC. When taking OTFC, you should talk to your dentist about proper care of your teeth. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of OTFC. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Oral Transmucosal Fentanyl Citrate (OTFC)?

- **Always keep OTFC in a safe place away from children and from anyone for whom it has not been prescribed.** Protect OTFC from theft.

- You can use the OTFC Child Safety Kit to help you store OTFC and your other medicines out of the reach of children. It is very important that you use the items in the OTFC Child Safety Kit to help protect the children in your home or visiting your home.
- If you were not offered a Child Safety Kit when you received your medicine, call PAR PHARMACEUTICAL at 1-800-828-9393 to request one.

The OTFC Child Safety Kit contains important information on the safe storage and handling of OTFC.

The Child Safety Kit includes:

- **A child-resistant lock** that you use to secure the storage space where you keep OTFC (See Figure 1).

- **A portable locking pouch** for you to keep a small supply of OTFC nearby. The rest of your OTFC must be kept in a locked storage space.
- Keep this pouch secured with its lock and keep it out of the reach and sight of children (See Figure 2).

- **A child-resistant temporary storage bottle** (See Figure 3).

- **Store OTFC** at room temperature, 59°F to 86°F (15°C to 30°C) until ready to use.
- **Do not freeze OTFC.**

- **Keep OTFC in the original sealed child-resistant blister package.** Do not open the blister package until you are ready to use OTFC.
- **Keep OTFC dry.**

How should I dispose of Oral Transmucosal Fentanyl Citrate (OTFC) units when they are no longer needed?

Disposing of OTFC units after use: Partially used OTFC units may contain enough medicine to be harmful or fatal to a child or other adults who have not been prescribed OTFC. **You must properly dispose of the OTFC handle right away after use even if there is little or no medicine left on it.** After you have finished the OTFC unit and the medicine is totally gone, throw the handle away in a place that is out of the reach of children.

- Place the used OTFC unit under hot running water until the medicine is gone, and then throw the handle away out of the reach of children and pets (See Figure 4).

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- Place the used OTFC unit under hot running water until the medicine is gone, and then throw the handle away out of the reach of children and pets (See Figure 4).



Figure 5
Disposing of Used OTFC Units from the Temporary Storage Bottle: You must dispose of all used OTFC units in the temporary storage bottle at least one time each day, as follows:

1. To open the temporary storage bottle, push down on the cap until you are able to twist the cap to the left to remove it (See Figure 6).
2. Remove one OTFC unit from the temporary storage bottle. Hold the OTFC by its handle over the toilet bowl.
3. Using wire-cutting pliers, cut a medicine end off so that it falls into the toilet.
4. Throw the handle away in a place that is out of the reach of children.
5. Repeat these 3 steps for each OTFC handle that is in the storage bottle. There should not be more than 4 handles in the temporary storage bottle for 1 day.
6. Flush the toilet twice.

Do not flush entire unused OTFC units, OTFC handles, or blister packages down the toilet.

Disposing of unopened OTFC units: Dispose of any unopened OTFC units remaining from a prescription as soon as they are no longer needed, as follows:

1. Remove all OTFC from the locked storage space (See Figure 7).

2. Remove one OTFC unit from its blister package by using scissors to cut off the marked end and then peel back the blister backing (See Figures 8A and 8B).

3. Hold OTFC by its handle over the toilet bowl. Use wire-cutting pliers to cut the medicine end off so that it falls into the toilet (See Figures 9A and 9B).

4. Throw the handle away in a place that is out of the reach of children (See Figure 10).

5. Repeat steps 1 through 4 for each OTFC unit.
6. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.

7. Repeat steps 1 through 4 for each OTFC unit.
8. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.

9. Repeat steps 1 through 4 for each OTFC unit.
10. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.

11. Repeat steps 1 through 4 for each OTFC unit.
12. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.

13. Repeat steps 1 through 4 for each OTFC unit.
14. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.

15. Repeat steps 1 through 4 for each OTFC unit.
16. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.

17. Repeat steps 1 through 4 for each OTFC unit.
18. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.

19. Repeat steps 1 through 4 for each OTFC unit.
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21. Repeat steps 1 through 4 for each OTFC unit.
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23. Repeat steps 1 through 4 for each OTFC unit.
24. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.

25. Repeat steps 1 through 4 for each OTFC unit.
26. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.

You can ask your pharmacist or healthcare provider for information about OTFC that is written for healthcare professionals. For more information about the TIRF REMS Access program, go to www.TIRFREMSAccess.com or call 1-866-822-1463.

What are the ingredients of Oral Transmucosal Fentanyl Citrate (OTFC)?
Active Ingredient: fentanyl citrate
Inactive Ingredients: Anhydrous citric acid, artificial raspberry flavor, confectioner's sugar, dextrose, dibasic sodium phosphate, FD&C blue no. 1, magnesium stearate, pregelatinized starch, propylene glycol and purified shellac.

Patient Instructions for Use
Before you use OTFC, it is important that you read the Medication Guide and these Patient Instructions for Use. Be sure that you read, understand, and follow these Patient Instructions for Use so that you use OTFC the right way. Ask your healthcare provider or pharmacist if you have any questions about the right way to use OTFC.

When you get an episode of breakthrough cancer pain, use the dose of OTFC prescribed by your healthcare provider as follows:

- You may drink some water before using OTFC but you should not drink or eat anything while using OTFC.
- Each unit of OTFC is sealed in its own blister package (See Figure 12). Do not open the blister package until you are ready to use OTFC.

When you are ready to use OTFC, cut open the package using scissors. Peel back the blister backing, and remove the OTFC unit (See Figures 13A and 13B). The end of the unit printed with "OTFC" and the strength number of the unit ("200", "400", "600", "800", "1200", or "1600") is the medicine end that is to be placed in your mouth. Hold the OTFC unit by the handle (See Figure 14).

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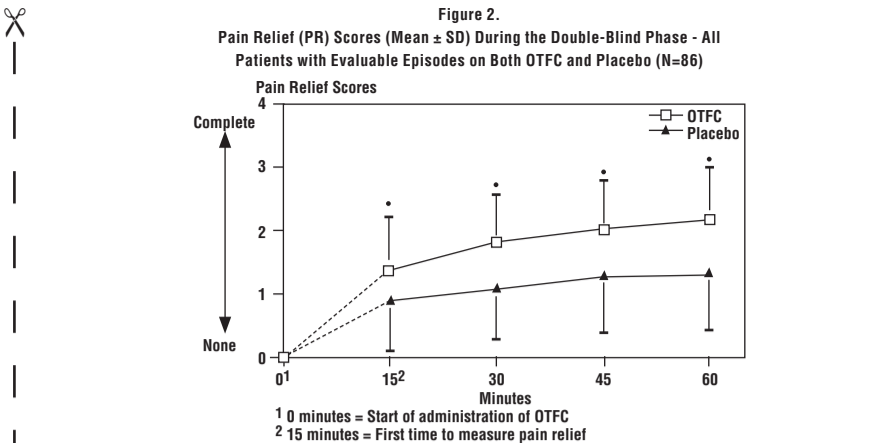
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16 HOW SUPPLIED/STORAGE AND HANDLING
16.1 Storage and Handling
Oral Transmucosal Fentanyl Citrate (OTFC) is supplied in individually sealed child-resistant blister packages. The amount of fentanyl contained in each unit can be fatal to a child. Patients and their caregivers must be instructed to keep OTFC out of the reach of children (See **Boxed Warning - Warning: Risk of Respiratory Depression, Medication Errors, Abuse Potential, Warnings and Precautions (5.2)**, and **Patient Counseling Information (7.1)**). Store at 20° to 25° (68° to 77°F) [See USP Controlled Room Temperature] until ready for use. Protect OTFC from freezing and moisture. Do not use if the blister package has been opened.

16.2 Disposal of OTFC
Patients must be advised to dispose of any units remaining from a prescription as soon as they are no longer needed. While all units should be disposed of immediately after use, partially consumed units represent a special risk because they are no longer protected by the child-resistant blister package, yet may contain enough medicine to be fatal to a child (See **Patient Counseling Information (7.5)**).

A temporary storage bottle is provided as part of the Oral Transmucosal Fentanyl Citrate (OTFC) Child Safety Kit (See **Patient Counseling Information (7.6)**). This container is to be used by patients or their caregivers in the event that a partially consumed unit cannot be disposed of promptly. Instructions for usage of this container are included in the **Medication Guide**. Patients and members of their household must be advised to dispose of any units remaining from a prescription as soon as they are no longer needed. Instructions are included in **Patient Counseling Information (7.5)** and in the **Medication Guide**. If additional assistance is required, call PAR PHARMACEUTICAL at 1-800-828-9393.

16.3 New Supplies
Oral Transmucosal Fentanyl Citrate (OTFC) is supplied in six dosage strengths. Each unit is individually wrapped in a child-resistant, anesthetic blister package. These blister packages are packed 30 per shelf carton for use when patients have been titrated to the appropriate dose. Each dosage unit has a white to off-white color. Each individual solid drug matrix is marked with "Fentanyl" and the strength of the unit: "200 mcg", "400 mcg", "600 mcg", "800 mcg", "1200 mcg", or "1600 mcg". The dosage strength is also marked on the handle tag, the blister package, and the carton. See blister package and carton for complete information.

Oral Transmucosal Fentanyl Citrate (OTFC) is supplied as white to off-white, round, cylindrical shaped lozenges attached to a fracture resistant plastic handle, as follows:
200 mcg: Imprinted Fentanyl over 200 mcg in blue ink, debossed with 1 on the convex (top) side and flat on the other (bottom) side.
30 Units (10 x 3 Blisters)
400 mcg: Imprinted Fentanyl over 400 mcg in blue ink, debossed with 2 on the convex (top) side and flat on the other (bottom) side.
30 Units (10 x 3 Blisters)
600 mcg: Imprinted Fentanyl over 600 mcg in blue ink, debossed with 3 on the convex (top) side and flat on the other (bottom) side.
30 Units (10 x 3 Blisters)
800 mcg: Imprinted Fentanyl over 800 mcg in blue ink, debossed with 4 on the convex (top) side and flat on the other (bottom) side.
30 Units (10 x 3 Blisters)
1200 mcg: Imprinted Fentanyl over 1200 mcg in blue ink, debossed with 5 on the convex (top) side and flat on the other (bottom) side.
30 Units (10 x 3 Blisters)
1600 mcg: Imprinted Fentanyl over 1600 mcg in blue ink, debossed with 6 on the convex (top) side and flat on the other (bottom) side.
30 Units (10 x 3 Blisters)

17 PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Medication Guide).

17.1 Patient/Caregiver Instructions
• Before initiating treatment with Oral Transmucosal Fentanyl Citrate (OTFC), explain the statements below to patients and/or caregivers. Instruct patients to read the Medication Guide each time OTFC is dispensed because new information may be available.
○ Outpatients must be enrolled in the TIRF REMS Access program before they can receive OTFC.
○ Allow patients the opportunity to ask questions and discuss any concerns regarding OTFC or the TIRF REMS Access program.
○ As a component of the TIRF REMS Access program, prescribers must review the contents of the OTFC Medication Guide with every patient before initiating treatment with OTFC.
○ Advise the patient that OTFC is available only from pharmacies that are enrolled in the TIRF REMS Access program, and provide them with the telephone number and website for information on how to obtain the drug.
○ Advise the patient that only enrolled healthcare providers may prescribe OTFC.
○ Patients must sign the Patient-Practitioner Agreement to acknowledge that they understand the risks of OTFC.
○ Advise patients that they may be requested to participate in a survey to evaluate the effectiveness of the TIRF REMS Access program.

• **Patients and their caregivers must be instructed that children exposed to OTFC are at high risk of FATAL RESPIRATORY DEPRESSION.** Patients and their caregivers must be instructed to keep OTFC out of the reach of children (See **How Supplied/Storage and Handling (16.1)**, **Warnings and Precautions (5.2 and 5.3)**, and **Medication Guide for specific patient instructions**).
• Provide patients and their caregivers with a Medication Guide and review it with them each time OTFC is dispensed because new information may be available.
• Instruct patients and their caregivers to keep both used and unused dosage units out of the reach of children. Partially consumed units represent a special risk to children. In the event that a unit is not completely consumed, it must be properly disposed of as soon as possible (See **How Supplied/Storage and Handling (16.1)**, **Warnings and Precautions (5.3)**, and **Patient Counseling Information (7.5)**).
• Instruct patients not to take OTFC for acute pain, postoperative pain, pain from injuries, headache, migraine or any other short-term pain, even if they have taken other opioid analgesics for these conditions.
• Instruct patients on the meaning of opioid tolerance and that OTFC is only to be used as a supplemental pain medication for patients with pain requiring around-the-clock opioids, who have developed tolerance to the opioid medication, and who need additional opioid treatment of breakthrough pain episodes.
• Instruct patients that, if they are not taking an opioid medication on a scheduled basis (around-the-clock), they should not take OTFC.
• Instruct patients that, if the breakthrough pain episode is not relieved 15 minutes after finishing the OTFC unit, they may take **ONLY ONE ADDITIONAL UNIT OF OTFC WITH THE SAME STRENGTH FOR THAT EPISODE. They, patients should take no more than two units of OTFC for any breakthrough pain episode.**
• Instruct patients that they MUST wait at least 4 hours before treating another episode of breakthrough pain with OTFC.
• Instruct patients NOT to share OTFC and that sharing OTFC with anyone else could result in the other individual's death due to overdose.
• Make patients aware that OTFC contains fentanyl, which is a strong pain medicine similar to hydromorphone, methadone, morphine, oxycodone, and oxycodone.
• Instruct patients that the active ingredient in OTFC, fentanyl, is a drug that some people abuse. OTFC should be taken only by the patient it was prescribed for, and it should be protected from theft and misuse in the work or home environment.
• Caution patients to talk to their doctor if breakthrough pain is not alleviated or worsens after taking OTFC.
• Instruct patients to use OTFC exactly as prescribed by their doctor and not to take OTFC more often than prescribed.
• Caution patients that OTFC can affect a person's ability to perform activities that require a high level of attention (such as driving or using heavy machinery). Warn patients taking OTFC of these dangers and counsel them accordingly.
• Warn patients to not combine OTFC with alcohol, sleep aids, or tranquilizers except by the order of the prescribing physician, because dangerous additive effects may occur, resulting in serious injury or death.
• Inform female patients that if they become pregnant during treatment with OTFC, they should ask their doctor about the effects that OTFC (or any medicine) may have on them and their unborn children.
• Physicians and dispensing pharmacists must specifically question patients or caregivers about the presence of children in the home (on a full time or visiting basis) and counsel them regarding the dangers to children from medication exposure.

17.2 Dental Care
Because each OTFC unit contains approximately 2 grams of sugar, frequent consumption may increase the risk of dental decay. The occurrence of dry mouth associated with the use of opioid medications (such as fentanyl) may add to this risk. Postmarketing reports of dental decay have been received in patients taking OTFC (See **Adverse Reactions (6.2)**). In some of these patients, dental decay occurred despite routine oral hygiene. Dental decay in cancer patients may be multi-factorial; patients using OTFC should consult their dentist to ensure appropriate oral hygiene.

17.3 Diabetic Patients
Advise diabetic patients that OTFC contains approximately 2 grams of sugar per unit.

17.4 OTFC Child Safety Kit
Provide patients and their caregivers who have children in the home or visiting with an Oral Transmucosal Fentanyl Citrate Child Safety Kit, which contains educational materials and safe interim storage containers to help patients store OTFC and other medicines out of the reach of children. To obtain a supply of Child Safety Kits, healthcare professionals can call PAR PHARMACEUTICAL at 1-800-828-9393.

17.5 Disposal of Used OTFC Units
Patients must be instructed to dispose of completely used and partially used OTFC units.
1. After consumption of the unit is complete and the matrix is totally dissolved, throw away the handle in a trash container that is out of the reach of children.
2. If any of the drug matrix remains on the handle, place the handle under hot running tap water until all of the drug matrix is dissolved, and then dispose of the handle in a place that is out of the reach of children.
3. Dispose of handles in the child-resistant container (as described in steps 1 and 2) at least once a day.
• If the patient does not entirely consume the unit and the remaining drug cannot be immediately dissolved under hot running water, the patient or caregiver must temporarily store the OTFC unit in the specially provided child-resistant container out of the reach of children until proper disposal is possible.

17.6 Disposal of Unopened OTFC Units When No Longer Needed
Patients and members of their household must be advised to dispose of any unopened units remaining from a prescription as soon as they are no longer needed.
To dispose of the unused OTFC units:
1. Remove the OTFC unit from its blister package using scissors, and hold the OTFC by its handle over the toilet bowl.
2. Using wire-cutting pliers cut off the drug matrix end so that it falls into the toilet.
3. Dispose of the handle in a place that is out of the reach of children.
4. Repeat steps 1, 2, and 3 for each OTFC unit. Flush the toilet twice after 5 units have been cut and deposited into the toilet. Do not flush the entire unused OTFC units, OTFC handles, blister packages, or cartons down the toilet. Dispose of the handle where children cannot reach it (See **How Supplied/Storage and Handling (16.1)**).

Detailed instructions for the proper storage, administration, disposal, and important instructions for managing an overdose of OTFC are provided in the OTFC Medication Guide. Encourage patients to read this information in its entirety and give them an opportunity to have their questions answered.

In the event that a caregiver requires additional assistance in disposing of excess unusable units that remain in the home after a patient has expired, instruct them to call the toll-free number for PAR PHARMACEUTICAL (1-800-828-9393) or seek assistance from their local DEA office. Fentora® is a registered trademark of Cephalon.

MEICATION GUIDE
Oral Transmucosal Fentanyl Citrate (FEN to nil SIT ray) Lozenge (OTFC)
200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg
(IMPORTANT: Do not use Oral Transmucosal Fentanyl Citrate (OTFC) unless you are regularly using another opioid pain medicine around-the-clock for at least one week or longer for your cancer pain and your body is used to these medicines (this means that you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant. Keep Oral Transmucosal Fentanyl Citrate (OTFC) in a safe place away from children. Get emergency medical help right away if:
• a child takes Oral Transmucosal Fentanyl Citrate (OTFC), Oral Transmucosal Fentanyl Citrate (OTFC) can cause an overdose and death in any child who takes it.
• an adult who has not been prescribed Oral Transmucosal Fentanyl Citrate (OTFC) uses it.
• an adult who is not already taking opioids around-the-clock, uses Oral Transmucosal Fentanyl Citrate (OTFC).
These are medical emergencies that can cause death. If possible, remove Oral Transmucosal Fentanyl Citrate (OTFC) from the mouth.

Read this Medication Guide completely before you start using OTFC and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.
What is the most important information I should know about Oral Transmucosal Fentanyl Citrate (OTFC)?
OTFC can cause life-threatening breathing problems which can lead to death:
1. **Do not use OTFC if you are not opioid tolerant.**
2. **If you stop taking your around-the-clock opioid pain medicine for your cancer pain, you must stop using OTFC.** You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
3. **Use OTFC exactly as prescribed by your healthcare provider.**
• You must not use more than 1 unit of OTFC at a time and no more than 2 units of OTFC during each episode of breakthrough cancer pain.
• You must wait at least 4 hours before treating a new episode of breakthrough pain. See the **Medication Guide section "How should I use OTFC?"** and the **Patient Instructions for Use at the end of this Medication Guide about how to use OTFC the right way.**
4. **Do not switch from OTFC to other medicines that contain fentanyl without talking with your healthcare provider.** The amount of fentanyl in a dose of OTFC is not the same as the amount of fentanyl in other medicines that contain fentanyl. Your healthcare provider will prescribe a starting dose of OTFC that may be different than other fentanyl containing medicines you may have been taking.
5. **Do not use OTFC for short-term pain that you would expect to go away in a few days, such as:**
• pain after surgery
• headache or migraine
• dental pain
6. **Never give OTFC to anyone else, even if they have the same symptoms you have. It may harm them or even cause death.** OTFC is a federally controlled substance (CII) because it has a strong opioid (paralytic) pain medicine that can be misused by people who abuse prescription medications or street drugs.
• Prevent theft, misuse or abuse. **Keep OTFC in a safe place** to protect it from being stolen. OTFC can be a target for people who abuse opioid (narcotic) medicines or street drugs.
• **Storing or giving away this medicine is against the law.**
7. OTFC is available only through a program called the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access program. To receive OTFC, you must:
• talk to your healthcare provider
• understand the benefits and risks of OTFC
• agree to all of the instructions
• sign the Patient-Practitioner Agreement form

What is Oral Transmucosal Fentanyl Citrate (OTFC)?
OTFC is a prescription medicine that contains the medicine fentanyl.
OTFC is used to manage breakthrough pain in adults (16 years of age and older) with cancer who are already routinely taking other opioid pain medicines around-the-clock for cancer pain.
OTFC is started only after you have been taking other opioid pain medicines and your body has become used to them (you are opioid tolerant). Do not use OTFC if you are not opioid tolerant.
• OTFC is a lozenge (attached to a handle) that you place between your cheek and lower gum and suck on to dissolve.
• You must stay under your healthcare provider's care while using OTFC.
• OTFC is only:
○ available through the TIRF REMS Access program
○ given to people who are opioid tolerant

It is not known if OTFC is safe and effective in children under 16 years of age.
Who should not use Oral Transmucosal Fentanyl Citrate (OTFC)?
Do not use OTFC:
• **If you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for at least one week or longer for your cancer pain, and your body is used to these medicines.**
• for short-term pain that you would expect to go away in a few days, such as:
○ pain after surgery
○ headache or migraine
○ dental pain
• if you are allergic to any of the ingredients in OTFC. See the end of this Medication Guide for a complete list of ingredients in OTFC.
• Patients must sign the Patient-Practitioner Agreement before using Oral Transmucosal Fentanyl Citrate (OTFC). Before using OTFC, tell your healthcare provider if you:
• have trouble breathing or lung problems such as asthma, wheezing, or shortness of breath
• have or had a head injury or brain problem
• have ever on any medicines
• have seizures
• have a slow heart rate or other heart problems
• have low blood pressure
• have mental problems including major depression, schizophrenia or hallucinations (seeing or hearing things that are not there)
• have a past or present drinking problem (alcoholism), or a family history of drinking problems
• have a past or present drug abuse or addiction problem, or a family history of a drug abuse problem or addiction problem
• have diabetes. Each OTFC unit contains about 1½ teaspoon (2 grams) of sugar.
• have any other medical conditions
• are pregnant or plan to become pregnant. OTFC may cause serious harm to your unborn baby.
• are breastfeeding or plan to breastfeed. OTFC passes into your breast milk. It can cause serious harm to your baby.