

071207.med guide solution final draftF-XXXXXXXX

MEDICATION GUIDE

INTRON® A

(Interferon alfa-2b, recombinant)

Including appendix with instructions for using INTRON A Solution for Injection

Read this Medication Guide carefully before you start to take INTRON A (In-tron aye) for Injection alone or INTRON A in combination with REBETOL (REB-eh-tole) (ribavirin, USP) Capsules. Read the Medication Guide each time you refill your prescription because there may be new information. The information in this Medication Guide does not take the place of talking with your healthcare provider.

If you are taking INTRON A and REBETOL combination therapy, also read the medication guide for REBETOL (ribavirin, USP) Capsules.

What is the most important information I should know about INTRON A?

INTRON A is a treatment for some people who have hairy cell leukemia, malignant melanoma, follicular lymphoma, AIDS-related Kaposi's sarcoma, chronic hepatitis B, chronic hepatitis C and condylomata acuminata. If you have chronic hepatitis C, your healthcare provider may prescribe INTRON A in combination with REBETOL. INTRON A used by itself or with REBETOL can help you, but can also have serious side effects and may cause death in rare cases. Before starting treatment, you should talk to your healthcare provider about the possible benefits and possible side effects of INTRON A alone or in combination with REBETOL, to decide if this treatment is right for you. While taking INTRON A alone or in combination with REBETOL, you need to see a healthcare provider regularly for medical examinations and lab tests to make sure the treatment is working and to check for side effects.

You should call your healthcare provider immediately if you develop any of these conditions while taking INTRON A:

- You become pregnant or if you are a male and your female partner becomes pregnant
- New or worsening mental health problems such as thoughts about hurting or killing yourself or others
- Decreased vision
- Trouble breathing or chest pain
- Severe stomach or lower back pain
- Bloody diarrhea or bloody bowel movements
- High fever
- Easy bruising or bleeding

The most serious possible side effects of INTRON A include:

49 **RISK TO PREGNANCY.** Combination INTRON A and REBETOL therapy can
50 cause death, serious birth defects or other harm to your unborn child. If you
51 are pregnant, you or your male partner must not take INTRON A and REBETOL
52 combination therapy. You must not become pregnant while either you or your
53 partner are taking the combination of INTRON A and REBETOL and for 6
54 months after you stop taking the combination. If you are a woman of
55 childbearing age you must have negative pregnancy tests immediately before
56 starting treatment, during treatment and for 6 months after you have stopped
57 treatment. You should use two forms of birth control during and for 6 months
58 after you have stopped treatment. If you are a man taking INTRON A/REBETOL
59 combination therapy, one of the two forms of birth controls should be a
60 condom. You must use birth control even if you believe that you are not fertile
61 or that your fertility is low. You should talk to your healthcare provider about
62 birth control for you and your partner. If you or your partner becomes
63 pregnant while either of you is being treated or within 6 months of stopping
64 treatment tell your healthcare provider right away. **There is a Ribavirin
65 Pregnancy Registry that collects information about pregnancy outcomes in
66 female patients and female partners of male patients exposed to ribavirin. You
67 or your healthcare provider are encouraged to contact the Registry at 1-800-
68 593-2214.**

69
70 **Mental health problems and suicide.** INTRON A may cause patients to develop
71 mood or behavioral problems. These can include irritability (getting easily upset)
72 and depression (feeling low, feeling bad about yourself, or feeling hopeless). Some
73 patients may have aggressive behavior. Former drug addicts may fall back into drug
74 addiction or overdose. Some patients think about hurting or killing themselves or
75 other people. Some patients have killed themselves (suicide) or hurt themselves or
76 others. You must tell your healthcare provider if you are being treated for a mental
77 illness or had treatment in the past for any mental illness, including depression and
78 suicidal behavior. You should also tell your healthcare provider if you have ever
79 been addicted to drugs or alcohol.

80
81 **Eye problems.** If you notice any changes in your eyesight such as difficulty seeing,
82 it could mean that your eyes are being affected, so you should call your healthcare
83 provider right away.

84
85 **Heart problems.** Some patients taking INTRON A may develop problems with their
86 heart, including low blood pressure, fast heart rate, and very rarely, heart attacks.
87 Tell your healthcare provider if you have had any heart problems in the past.

88
89 **Blood problems.** INTRON A commonly lowers two types of blood cells (white
90 blood cells and platelets). In some patients, these blood counts may fall to
91 dangerously low levels. If your blood cell counts become very low, you could get
92 infections or have bleeding problems.

93
94 If you are taking INTRON A and REBETOL combination therapy, REBETOL can
95 cause a drop in your number of red blood cells (anemia). A very low red blood cell
96 count can be dangerous especially if you have heart or breathing problems.

97 For other possible side effects of INTRON A. see *"What are the possible side*
98 *effects of INTRON A?" in this Medication Guide.*

99 **What is INTRON A?**

100
101 The INTRON A product contains a man-made protein called interferon. Interferon is
102 a protein that is part of the body's immune system that "interferes" with the growth of
103 viruses or cancer cells.

104
105 It is not known if INTRON A or INTRON A/REBETOL combination therapy can cure
106 hepatitis B or C (permanently eliminate the virus) or if it can prevent liver failure or
107 liver cancer that is caused by hepatitis B or C infection.

108
109 It is also not known if INTRON A or INTRON A/REBETOL combination therapy will
110 prevent one infected person from infecting another person with hepatitis B or C.

111
112 **Who should not take INTRON A?**

113
114 Do not take the INTRON A alone or in combination with REBETOL if you:

- 115
116 • are pregnant, planning to get pregnant, or breast-feeding.
117 • are a male patient on combination therapy and have a female sexual partner who
118 is pregnant or plans to become pregnant while you are being treated with
119 REBETOL or during the 6 months after your treatment has ended.
120 • have autoimmune hepatitis (hepatitis caused by your immune system attacking
121 your liver) or unstable liver disease (yellowing of the skin and eyes, swelling of
122 the abdomen).
123 • had an allergic reaction to another alpha interferon or ribavirin or are allergic to
124 any of the ingredients in INTRON A or REBETOL.

125
126 **If you have any of the following conditions or serious medical problems, tell**
127 **your healthcare provider before taking INTRON A alone or in combination with**
128 **REBETOL:**

- 129 • depression or anxiety
130 • eye problems
131 • sleep problems
132 • high blood pressure
133 • previous heart attack, or other heart problems
134 • liver problems (other than hepatitis B or C)
135 • any kind of autoimmune disease (where the body's immune system attacks the
136 body's own cells), such as psoriasis, sarcoidosis, systemic lupus erythematosus,
137 rheumatoid arthritis
138 • thyroid problems
139 • diabetes
140 • colitis (inflammation of the bowels)
141 • cancer
142 • hepatitis B or C infection
143 • HIV infection (the virus that causes AIDS)
144 • kidney problems
145 • bleeding problems

- 146 • alcoholism
- 147 • drug abuse or addiction
- 148 • body organ transplant and are taking medicine that keeps your body from
- 149 rejecting your transplant (suppresses your immune system).
- 150 • high blood triglycerides (fat particles normally found in your blood)

151

152 How should I take INTRON A?

153

154 To get the most benefit from this medicine, it is important that you take INTRON A
155 exactly as your healthcare provider tells you. Your healthcare provider will decide
156 your dose of INTRON A and how often you will take it. Do not take more than your
157 prescribed dose. INTRON A is given as an injection either under the skin
158 (subcutaneous) or into a muscle (intramuscular). You should be completely
159 comfortable with how to prepare and measure your dose of INTRON A and how to
160 inject yourself before you use INTRON A for the first time. Your healthcare provider
161 will train you on how to use and inject INTRON A properly.

162

163 INTRON A comes in different strengths and different forms (a powder in a vial, a
164 solution in a vial and a multidose pen). Your healthcare provider will determine which
165 form is best for you. The instructions for giving a dose of INTRON A are at the end of
166 this leaflet.

167

168 If you miss a dose of INTRON A, take the missed dose as soon as possible during
169 the same day or the next day, then continue on your regular dosing schedule. If
170 several days go by after you miss a dose, check with your healthcare provider to see
171 what to do. **Do not double your next dose** or take more than your prescribed dose
172 without talking to your healthcare provider. Call your healthcare provider right away if
173 you take more than your prescribed dose. Your healthcare provider may wish to
174 examine you more closely and take blood for testing.

175

176 If you are taking INTRON A in combination with REBETOL, you should also read the
177 Medication Guide for REBETOL (ribavirin, USP) for more information about side
178 effects and how to take REBETOL. **REBETOL capsules should be taken twice a**
179 **day with food.** Taking REBETOL with food helps your body take up more of the
180 medicine. Taking REBETOL at the same time of day every day will help keep the
181 amount of medicine in your body at a steady level. This can help your healthcare
182 provider decide how your treatment is working and how to change the number of
183 REBETOL capsules you take if you have side effects. If you miss a dose of
184 REBETOL, take the missed dose as soon as possible during the same day. If an
185 entire day has passed, check with your healthcare provider about what to do. **Do not**
186 **double your next dose.**

187 You must see your healthcare provider on a regular basis for blood tests so your
188 healthcare provider can check how the treatment is working for you and to check for
189 side effects.

190

191 Tell your healthcare provider if you are taking or planning to take other prescription
192 or non-prescription medicines, including vitamin and mineral supplements and
193 herbal medicines.

194
195
196
197
198
199
200
201
202
203
204
205
206
207
208
209
210
211
212
213
214
215
216
217
218
219
220
221
222
223
224
225
226
227
228
229
230
231
232
233
234
235
236
237
238
239
240
241

What should I avoid while taking INTRON A?

- Avoid becoming pregnant while taking INTRON A. INTRON A alone and INTRON A taken in combination with REBETOL may harm your unborn child or cause you to lose your baby (miscarry). If you or your partner becomes pregnant during treatment or during the 6 months after treatment with INTRON A/REBETOL combination therapy, immediately report the pregnancy to your healthcare provider. Your healthcare provider will make decisions about your treatment. Your healthcare provider should call 1-800-593-2214. Your healthcare provider will be asked to give follow-up information about the pregnancy.
- Do not breast-feed your baby while taking INTRON A.

What are the possible side effects of INTRON A?

Possible, serious side effects include:

- **Risk to pregnancy, mental health problems, including suicide, blood problems, heart problems and eye problems.** see "What is the most important information I should know about INTRON A?"
- **Other body organ problems.** Certain symptoms like severe pain in the middle of your body, nausea, and vomiting may mean that your liver or pancreas is being damaged. A few patients have lung problems such as pneumonia (inflammation of the lung tissue), and inflammation of the kidney. If you are short of breath, coughing or have severe stomach or back pains or a fever, you should call your healthcare provider right away.
- **Thyroid problems.** Some patients develop changes in the function of their thyroid. Symptoms of thyroid changes include the inability to concentrate, feeling cold or hot all the time, a change in your weight and changes to your skin.
- **New or worsening autoimmune disease.** Some patients taking INTRON A develop autoimmune diseases (a condition where the body's immune cells attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus erythematosus, sarcoidosis, and psoriasis. In some patients who already have an autoimmune disease, the disease may worsen while on INTRON A.

Common but less serious side effects include:

- **Flu-like symptoms.** Most patients who take INTRON A have "flu-like" symptoms (headache, muscle aches, tiredness, and fever) that usually lessen after the first few weeks of therapy. You can reduce some of these symptoms by injecting your INTRON A dose at bedtime. Over-the-counter pain and fever medications can be used to prevent or reduce the fever and headache. If your fever does not go away you should tell your healthcare provider.
- **Extreme fatigue (tiredness).** Many patients become extremely tired while on INTRON A.
- **Appetite problems.** Nausea, loss of appetite, and weight loss, occur commonly.
- **Blood sugar problems.** Some patients develop problems with the way their body controls their blood sugar and may develop high blood sugar or diabetes.

- 242 • **Skin reactions.** Redness, swelling, and itching are common at the site of
243 injection. If after several days these symptoms do not disappear, contact your
244 healthcare provider. You may get a rash during therapy. If this occurs, your
245 healthcare provider may recommend medicine to treat the rash.
246
- 247 • **Hair thinning.** Hair thinning is common during INTRON A treatment. Hair loss
248 stops and hair growth returns after therapy is stopped.
249

250 These are not all the side effects of INTRON A or INTRON A/REBETOL combination
251 therapy. Your healthcare provider can give you a more complete list.
252

253 **General advice about prescription medicines**

254 Medicines are sometimes prescribed for purposes other than those listed in a
255 Medication Guide. If you have any concerns about the INTRON A product, you're
256 your healthcare provider. Your health care provider can give you additional
257 information about INTRON A. Do not use INTRON A for a condition for which it was
258 not prescribed. Do not share this medication with other people.
259

260
261 This Medication Guide has been approved by the U.S. Food and Drug
262 Administration.
263

264 Manufactured by: Schering Corporation Kenilworth, NJ 07033 USA
265

266 Issued: July 2007
267

268 *Safety-Lok is a trademark of Becton Dickinson and Company
269

270 Copyright © 1996, 2001, Schering Corporation.
271

271 All rights reserved.
272

272 Rev. 11/03
273

B-XXXXXXXX

274 **Medication Guide Appendix: Instructions for Preparing and Giving a Dose of** 275 **INTRON A Solution for Injection** 276

- 277 • INTRON A medication has been supplied to you in a liquid form in a vial.
278

279 **The INTRON A Solution for Injection may be supplied to you as either:**
280

- 281 • **INTRON A Solution in a Pak-10 (10 million IU) package.** This package
282 contains 6 single-use INTRON A vials of solution, 6 single-use disposable
283 Safety-Lok* syringes, and 12 alcohol swabs.
284

- 285 • **INTRON A Solution 18 million IU and 25 million IU multidose vial.** These
286 packages contain 1 vial of INTRON A solution. Syringes are not supplied to you.
287 Talk to your healthcare provider about what syringes you should use.
288

289 **Storing INTRON A Solution for Injection**

290 INTRON A Solution for Injection should be stored in the refrigerator between 2° and
291 8°C (36° and 46°F). **DO NOT FREEZE.** If you are using the Pak-10, 10 Million IU
292 single use vials discard any unused INTRON A solution remaining after use. If you
293 are using the 18 or 25 million IU multidose vials discard any unused INTRON A
294 solution remaining after one month.

295

296 **Preparing a Dose of INTRON A Solution for Injection**

297

298 1. Find a well lit, clean, flat working surface such as a table. Collect the supplies
299 you will need for an injection:

300

- 301 • A vial of INTRON A solution
- 302 • A single-use disposable Safety-Lok* syringe (provided in the "Pak-10") only,
303 or a syringe you have obtained for use with the multi-use vials
- 304 • A cotton ball or gauze
- 305 • Two alcohol swabs
- 306 • A puncture-proof disposable container

307

308 2. Before removing contents from the carton, check the expiration date printed on
309 the carton to make sure that the expiration date has not passed. Do not use if
310 the expiration date has passed.

311 3. Wash your hands with soap and warm water. It is important to keep your work
312 area, your hands and injection site clean to minimize the risk of infection.

313 4. If you are using the Pak-10 packages remove one vial of INTRON A solution, one
314 Safety-Lok* syringe and two alcohol swabs from the "Pak".

315 5. Check the vial of INTRON A. The solution should be clear and colorless, without
316 particles. Do not use the vial of INTRON A if the medicine is cloudy, has
317 particles or is any color beside clear and colorless.

318 6. Remove the protective plastic cap from the top of the INTRON A vial. Clean the
319 rubber stopper on the top of the INTRON A vial with an alcohol swab.

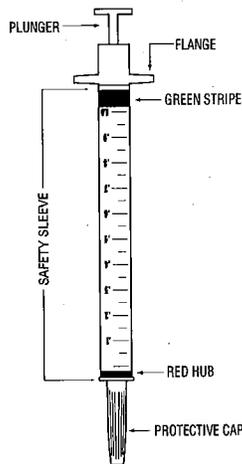
320 7. Gently warm the INTRON A solution by slowly rolling the vial in the palms of your
321 hands for about one minute. **DO NOT SHAKE.**

322 8. If you are using the Pak-10 packages, remove the protective wrapper from the
323 Safety-Lok* syringe. The Safety-Lok* syringe has a clear safety sleeve. The
324 safety sleeve should fit snugly against the flange (finger grip area of syringe) and
325 only be moved over the needle when ready for disposal.

326

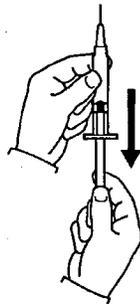
327 If you are using the multidose vials, open the package for the syringe you are using
328 and if it does not have a needle attached, then attach one of the needles you have
329 obtained to the syringe.

330
331

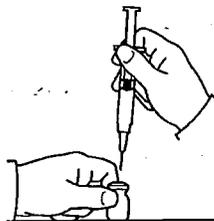


332
333
334
335
336
337
338
339
340
341
342
343
344
345
346
347
348

9. Remove the protective cap from the needle of the syringe. Fill the syringe with air by pulling the plunger back to the mark on the syringe that matches the dose as prescribed by your healthcare provider.

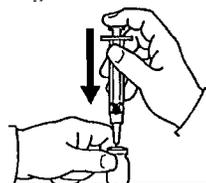


- 349 10. Hold the vial of INTRON A Solution for Injection on your flat working surface without touching the cleaned rubber stopper with your hands.



351
352
353
354
355
356
357
358
359

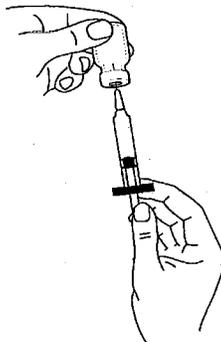
- 360 11. Insert the needle straight down through the middle of the rubber stopper of the vial containing the INTRON A solution. Slowly inject all the air from the syringe into the air space above the solution.



361
362
363
364
365
366

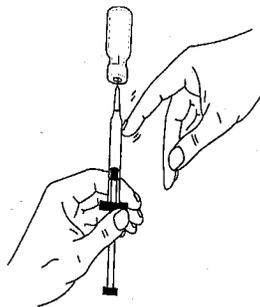
367
368
369
370
371
372

12. Keep the needle in the vial and turn the vial upside down. Make sure the tip of the needle is in the INTRON A solution. Slowly pull the plunger back to fill the syringe with INTRON A solution to the number (mL or cc) as prescribed by your healthcare provider.



373
374
375
376
377
378
379
380
381

13. With the needle in the vial, check the syringe for air bubbles. If there are any air bubbles, gently tap the syringe with your finger until the air bubbles rise to the top of the syringe. Slowly push the plunger up to remove the air bubbles. If you push solution back into the vial, slowly pull back on the plunger to again draw the correct dose as prescribed by your healthcare provider.



382
383
384
385
386
387
388

14. Do not remove the needle from the vial. Lay the vial and syringe on its side on your flat work surface until you are ready to inject the INTRON A solution.

Choosing an Injection site

389
390
391
392
393
394
395

Based on your treatment, your healthcare provider will tell you if you should inject a dose of INTRON A subcutaneously (under the skin) or intramuscularly (into the muscle). If it is too difficult for you to inject, ask someone who has been trained to give injections to help you.

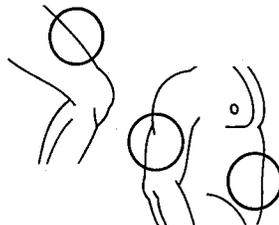
396
397
398

FOR SUBCUTANEOUS INJECTION

The best sites for injection are areas on your body with a layer of fat between skin and muscle such as:

399
400
401
402
403
404

- the front of your middle thighs
- the outer area of your upper arms
- the abdomen, except around the navel

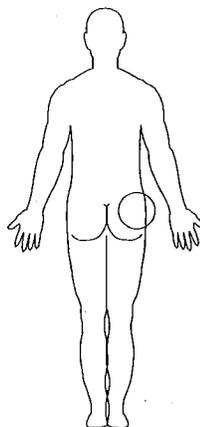
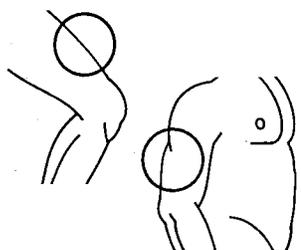


405
406
407
408
409
410
411
412
413
414
415
416

FOR INTRAMUSCULAR INJECTION

The best sites for injection into your muscle are:

- the front of the middle thighs
- the upper arms
- the upper outer areas of the buttocks



417
418
419
420
421
422
423
424
425
426
427
428
429
430

You should use a different site each time you inject INTRON A to avoid soreness at any one site. Do not inject INTRON A into an area where the skin is irritated, red, bruised, infected or has scars, stretch marks or lumps.

Injecting the Dose of INTRON A

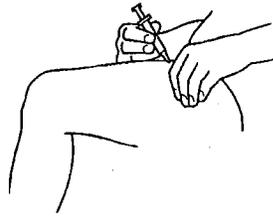
1. Clean the injection site with a new alcohol swab.
2. Pick up the vial and syringe from your flat work surface. Remove the syringe and needle from the vial. Hold the syringe in the hand that you will use to inject INTRON A. Do not touch the needle or allow it to touch the work

431 surface. If you are using a Safety-Lok* syringe, make sure the safety sleeve
432 is pushed against the syringe flange so that the needle is fully exposed.
433

434 3. With your free hand, pinch a fold of the skin at the cleaned injection site.
435

436 **FOR SUBCUTANEOUS INJECTION:**
437

438 4b. Hold the syringe (like a pencil) at a **45-degree angle** to the skin. With a quick
439 "dart-like" motion, push the needle into the skin.
440



441
442
443
444
445
446
447
448
449
450
451
452
453
454

455 **FOR INTRAMUSCULAR INJECTION:**
456

457 4b. Hold the syringe (like a pencil) at a **90-degree angle** to the skin. With a
458 quick "dart-like" motion, push the needle into the muscle.
459



460

461
462
463
464
465
466
467
468
469
470
471

5. After the needle is in, remove the hand used to pinch the skin and use it to hold the syringe barrel. Pull the plunger back slightly. If blood comes into the syringe, the needle has entered a blood vessel. **Do not inject INTRON A.** Withdraw the needle and discard the syringe in the puncture-proof container. See "*How should I dispose of materials used to inject INTRON A?*") Prepare a new dose of INTRON A and prepare a new injection site.

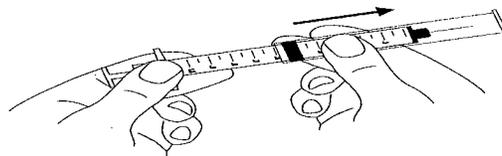
6. If no blood is present in the syringe, inject the medicine by gently pushing the plunger all the way down until the syringe is empty.

- 472 7. When the syringe is empty, pull the needle out of the skin and place a cotton ball
473 or gauze over the injection site and press for several seconds. Do not massage
474 the injection site. If there is bleeding, cover the injection site with a bandage.
475 8. Dispose of syringe and needle. See *"How should I dispose of materials used to*
476 *inject INTRON A?"*
477 9. If you are using a single-use vial (10 million IU), discard the INTRON A vial and
478 any remaining solution after use. If you are using a multidose vial (18 million IU
479 or 25 million IU) and there is enough solution left in the vial for another dose,
480 refrigerate the INTRON A vial after use. Discard any unused INTRON A solution
481 remaining after one month.
482 10. It is important to check your injection site approximately two hours after your
483 injection for redness, swelling, or tenderness. These are signs of inflammation
484 that you may need to talk to your healthcare provider about if they do not go
485 away.
486

487 **How should I dispose of materials used to inject INTRON A?**

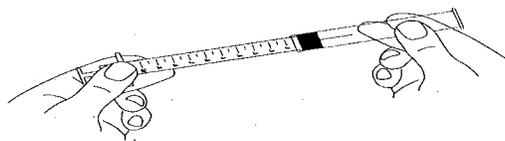
488 There may be special state and local laws for disposal of used needles and
489 syringes. Your healthcare provider should provide you with instructions on how to
490 properly dispose of your used syringes and needles. Always follow those
491 instructions. The instructions below should be used as a general guide for proper
492 disposal.
493

- 494 • **The needles and syringes should never be reused**
495
496 • **Disposing of the Safety-Lok* syringe.** To dispose of the Safety-Lok* syringe,
497 hold the flange of the syringe with one hand. Grasp the safety sleeve with your
498 free hand, sliding it completely over the needle. The green stripe on the safety
499 sleeve should cover the red hub of the needle and fit snugly.
500



501

502



503

504

- 505 • Place all used needles and syringes in a puncture-proof disposable container
506 that is available through your pharmacy or healthcare provider. You may also use
507 a hard plastic container with a screw-on cap (like a laundry detergent container).
508 DO NOT use glass or clear plastic containers for disposal of needles and
509 syringes.

- 510 • The container used for the disposal of syringes, needles, and Safety-Lok*
511 syringes should be clearly labeled as "USED SYRINGES AND NEEDLES."
512 When the container is almost full, tighten the lid. Tape the cap or lid to make
513 sure it does not come off. Dispose of the container as instructed by your
514 healthcare provider.
515 DO NOT throw the container in your household trash and DO NOT recycle.
516
517 • **Always keep the container out of reach of children.**