

METHYL-B₁₂ INJECTION INSTRUCTIONS

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PLEASE NOTE: YOUR CHILD'S DOSE IS THE CONTENT OF ONE PRE-FILLED SYRINGE

I. KEY POINTS UNDERLYING SUCCESS OR FAILURE:

- A) *All types of fat are not equal and different types of fats have different dissolution and dispersion constants.* From my studies, the fat from the region of the buttocks significantly outperforms the results of injections made into the fat of the arms, legs, or belly.
- B) Because my clinical research indicates *the methyl-B₁₂ phenomenon is due to a dependency condition, not a deficiency syndrome*, subcutaneous injections into the fat of the buttocks allows for a leaching effect that can provide a “24/7” slow release into the tissues. By contrast, injections into muscle quickly saturate B₁₂ receptors, correct any deficiency that may be occurring, and temporarily treat any dependency that is also present. After the B₁₂ receptors are saturated, the excess methyl-B₁₂ not bound to receptors will be filtered from the blood by the kidneys and excreted into the urine within 30-45 minutes after the injection. If the volume of the red methyl-B₁₂ shot is large enough, the next urine specimen will be red or it will be some color of red depending on the concentration of the urine, e.g. pink, pinkish-orange, etc. If, however, the volume of the red methyl-B₁₂ shot is small, the urine will not show red or pink even though the methyl-B₁₂ is filtered through the kidney into the urine within the same 30-45 minutes after being injected. Unfortunately the effects of intramuscular injections are quite confusing to parents and clinicians. Many children will show a response to some degree, often to a very noticeable degree. However, when compared to subcutaneous shots to the buttocks, the duration of the response is shorter; the intensity of the response, over time, will be less; and because of this combination of factors, many parents will discontinue shots months prematurely before realizing the full effect of methyl-B₁₂ for their child.

A couple of additional points must be made about intramuscular injections. Should you give your child a shot and see a response within minutes or a couple hours instead of many hours to days, you are giving the injections intramuscularly. Subcutaneous adipose tissue in the buttocks is not vascular enough to deliver enough methyl-B₁₂ fast enough to produce a significant clinical response in such a short period of time. If my dosing schedule is being followed and you see that the urine is pink, orange or red, the methyl-B₁₂ shot was undoubtedly delivered into the muscle no matter how much you believe the injection was given subcutaneously. Subcutaneous injections cannot deliver enough “red” methyl-B₁₂ fast enough to be cleared by the kidney and show red in the urine unless the volumes are huge, significantly greater than any that I commonly use.

[Addendum 2016: I have also learned that if the shot is given so shallowly that it is delivered just under the epidermis, the very top layer of skin, some of the red methyl-B₁₂ will then be delivered to the vascular system by the lymph which results in the same red to pink to orange-colored urine. Knowing that fact, I now advise parents to do their best to deliver the shot at an angle somewhere between 10 degrees to 20 degrees. Due to “the real world we live in”, this is not always possible so do the best you can in an “attempt to average” the 10 degree to 20 degree angle recommended.]

- C) Because of the above discussions, a constant steady state can be achieved in most individuals with a shot frequency being adequate once every three days if fat from the child's buttocks is used. I use the following example, not to be gross or disgusting, but rather because it allows you to easily visualize and remember the concept. To visualize what happens to a methyl-B₁₂ shot in the fat in the buttocks may be hard to do unless we ‘magnify it’. Therefore, let's think about an “elephant's butt” instead. Let's say there are 12 inches of fat between the skin and the muscle below. Our goal is to insert a red lollipop right in the middle of this elephant butt fat – 6 inches under the skin and 6 inches above the muscle. Because fat is moist and because lollipops dissolve whenever they come in contact with moisture, imagine the diameter of the lollipop gradually getting smaller and smaller until it is totally gone 3 days later. This is analogous to

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injecting a dense concentration of methyl-B₁₂ into the subcutaneous fat in a child's buttocks – a process of slow steady release over 3 days. By contrast let's revisit the elephant's butt and insert the lollipop in the muscle. Because muscle has lymph and blood constantly in motion, the lollipop continually has blood and lymph "washing over it" and the lollipop will dissolve much more quickly, similar to what would happen if it were in a bowl of water that was gently being rocked back and forth. As this illustration shows, the lollipop in the bowl will be completely melted within an hour. Should the lollipop have been inserted right at or very close to the subcutaneous/muscular junction, an effect somewhere in between the two extremes would be noted.

[Addendum 2016: I have also learned that approximately 70% of my children do better with daily shots than with every three day shots. This does not necessarily mean that a constant steady state was not achieved but rather that some children's metabolic rate is faster and therefore daily shots are necessary to "feed the hungry dependency state" that exists (as contrasted to a deficiency state described in "b" above). I have also found that I cannot rush getting to daily shots but must first make sure that the child is adequately primed with certain amounts of key supplements and that the child as been on every three day shots for no less than three months.]

D) Clinically speaking, methyl-B₁₂ injections, when truly delivered into fatty tissue in the buttocks, appear to disperse over a 3-day period "on average". Therefore, the first place you need to look when the benefits of a methyl-B₁₂ shot seem to wear off too soon is to retry the shots at the same dose and frequency but make the angle of attack much shallower, much closer to the horizontal plane, just under the skin. *[Addendum 2016: see the discussion in "B" above regarding shots being too shallow. At this point in time I recommend no less than a 10 degree angle for the shot.]* In children that are extremely thin or extremely young that have essentially no fatty tissue on their buttocks, I have found that injections given every day or every-other-day, still just under the skin, seem to overcome the problem and allow the benefits of methyl-B₁₂ to be seen. However, I do not keep the dose the same. Instead I make the dose of each shot proportionately less depending on whether it is given every other day or every day. For example, a dose of 750 mcg per shot every 3 days is equivalent to a shot of 500 mcg given every other day and equivalent to a shot of 250 mcg given daily.

E) *Common errors in technique:*

- a. *Pinching the fat:* Professionals often teach parents to "pinch the fat" to give a subcutaneous injection. Unfortunately with small children, the "tenting effect" that occurs not only brings with it subcutaneous fatty tissue but also "a ribbon of muscle" that is just as likely, if not more likely to receive the medication that is thought to be being administered into the subcutaneous tissue. The discussion above has already shown that from my clinical experience intramuscular injections are significantly inferior to those received in the fat in the buttocks. Therefore, **NEVER PINCH THE FAT** to insure a subcutaneous injection. Instead, go as shallow as necessary, often just under the skin in order to deliver the methyl-B₁₂ into subcutaneous tissue.
- b. *Angle of injection too vertical:* As discussed above in detail, the angle of injection may not be shallow enough in young children who have very little fat to deal with in order to hit fatty tissue and not muscle. Therefore, the thinner the child, the more closely the angle of the shot should be to the horizontal than the vertical plane as it enters the skin. At times you may need to **inject just under the surface of the skin** to accomplish this goal. *[Addendum 2016: see the discussion in "B" above regarding shots being too shallow. At this point in time I recommend no less than a 10 degree angle for the shot.]*

F) *Safety issues:*

- a. *The safety of the shots is unquestioned if administered from a **BD #328438 needle**.* This needle is only 8 mm in length and when the shot is given at a 30 degree or less, as was the technique previously taught, the "effective length" is only a small fraction of the original 8 mm length. (I now teach parents to give the shots very shallowly, just under the skin, e.g. a 10-20 degree angle.)
- b. Clinicians have always taught patients to use the upper outer quadrant of the buttocks to avoid injury to the sciatic nerve that could be reached if a regular sized needle was used in the lower portion of the buttocks. However, with the **BD #328438 extremely short needle** length of 8 mm,

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even if injected “straight in” over the area of the sciatic nerve, the chances of hitting it in anyone except the smallest preemie is impossible. With the angle of injection being anything significant, *it is impossible to hit the sciatic nerve.*

- c. By applying simple trigonometry, one of the professionals whose child is a patient of mine gave me this “rule of thumb” if a BD #328438 needle is used as per my protocol:
 - i. Shots injected at a 30 degree angle give an effective needle length of approximately 4 mm.
 - ii. Shots injected at a 20 degree angle give an effective needle length of approximately 2.7 mm.
 - iii. Shots injected at a 10 degree angle give an effective needle length of approximately 1.4 mm.
 - iv. Shots injected just under the skin give an effective needle length of 1 mm or less.
- d. Also, because the diameter of the **BD #328438 needle** is extremely small, “even if it hit the sciatic nerve” (which will never happen), it would cause no permanent injury.

II. Special Consideration Regarding the Local Anesthetic You Have Purchased

Do This before Administering Your First Shot

Parents are able to obtain different types of local anesthetic creams from different compounding pharmacies as prescribed by different clinicians. Clinicians “have their favorites”. Some are commercially available and are standardized as to effectiveness. Those produced by different compounding pharmacies can have different percentages of ingredients and different combination of ingredients. Therefore, some local anesthetics will act more quickly and/or wear off more quickly.

Therefore, what I suggest for my parents to do is the following:

- Make a chart showing the time in from 0 to 60 minutes in 5 minute increments.
- Rub a generous amount of the anesthetic cream onto the skin at the most sensitive portion of the upper inner thighs.
- Touch the area with firm pressure from a pin (do not break the skin) every 5 minutes to determine how long it takes to become numb and how long it takes before the numbness wears off.
- With such a chart, parents will know with confidence how long they should wait before they give their child the shot and how much time they have before the local anesthetic will no longer be active should they delay giving the shot for any reason.

III. A Couple Things That May Cause You Concern

- A. Occasionally I receive calls from parents concerned about a bluish or reddish discoloration under the skin and they are worried that this is a bad thing, that they have hurt their child, or that the dark spot will be permanent. The explanation for this is as follows:
 - a. Methyl-B₁₂ is a deep red color. Everyone knows that blood is dark red. When blood is viewed “through skin” it has a bluish tone. The shallower the angle of the needle, the more likely one is to at least see the color of the medicine or a tiny drop of blood that extruded from a capillary that was close to the injection site.

- b. Occasionally the needle punctures a very small capillary and a tiny drop of blood extrudes into the surrounding tissue. The “blue blood” plus the “red methyl-B₁₂” plus the child’s “individual skin tone” will produce some type of dark discoloration. I call it a “**methyl-B₁₂ tattoo.**”
- c. **This is a harmless phenomenon** and unlikely to repeat itself for the majority of shots unless the shots are always being given at the most extreme angle, almost horizontal in nature. When this happens, most of the discoloration seen is that of the medicine and not from the occasional nick of a capillary.

[Addendum 2016: see the discussion in “B” above regarding shots being too shallow. At this point in time I recommend no less than a 10 degree angle for the shot.]

- d. It should be noted that this small capillary bleed occurs with the same frequency when shots are given deeper. The only difference is that you can’t see it. Therefore the old saying, “Out of sight, out of mind” definitely applies to this situation.
- B. A child may feel a shot administered perfectly *if no local anesthetic was used*. The reason for this is because all of us have tiny nerve fibrils that are so small that no one can predict where these fibrils will be in order to miss them when giving a shot. Therefore, a shot administered quickly and without the cream will typically not be felt. However, occasionally the needle itself or the methyl-B₁₂, because of its pH, will be close enough to a nerve fibril that slight pain will be encountered. This pain is a very brief, fleeting pain and nothing to worry about because on a pain scale of 0-10 [0 = none; 10 = severe], the rating should be no higher than a 1-2 depending on the sensitivity of the child. This type of pain should be gone within 30 to 90 seconds. *It would be analogous to the degree of pain one feels from a mosquito bite.*
- C. Another possible scenario exists *if no local anesthetic was used*, that being that the shot is so close to these nerve fibrils that the volume of the shot causes a *local “stretching” of the nerve fibrils*. When nerve fibrils are stretched, mild pain results. *This is similar to having a pimple, what I call “the zit pressure effect”*. As is well known, as long as a pimple is exerting pressure, there is pain. Once the pimple is popped, the pain goes away. So it is with the zit pressure effect from a shot close to a nerve fibril. This pain may last for a few minutes while the excess fluid causing the stretching is being reabsorbed into the body tissue. The effect of this problem is more like a 1.5 to 2 on the pain scale.
- D. Still another possible scenario exists *if no local anesthetic was used*, that being that the shot is so shallow that not only does one have the possibility of being near a subcutaneous nerve fibril, but in addition one is so close to the skin that a small “medicine bubble” pops up. This small bleb is totally safe but the skin has a much greater density of nerve fibrils than one finds in the adipose tissue of the buttocks. Therefore, this problem may occur more often with extremely shallow shots. The effect of this problem is more like a 2 to 3 on the pain scale. Its effect will also last for only a few minutes before the effect resolves. This only happens with larger shot volumes used for bigger children and only if numbing cream has not been used.
- E. When pain is prolonged or more than mild, it is usually the result of a pH problem due to a bad batch of methyl-B₁₂ shots. I have discussed this in detail in the section below entitled “Pain – Pain – Pain”. As you will see from our videos, we are not trying to hide anything, nor are we trying to make you believe that life is perfect with the shots and that you will never have anything go wrong. However, the problems are so minor and so infrequent compared to the benefit most parents see that, with few exceptions, parents say that they can live with whatever isn’t perfect while they are getting their child back.

[Addendum 2016: over the last decade I have been able to observe what happens with shots from Hopewell Pharmacy as well as hundreds of compounding pharmacies making injectable methyl-B₁₂ for their patients. From the data we have followed, it is now my “stronger than ever” belief that the pH of the methyl-B₁₂ is the greatest factor resulting in pain. Also, it is always my observation that pH not only affects whether a shot is painful or not but also the effectiveness of the shot. In addition, there are multiple suppliers for the methyl-B₁₂ raw material that compounding pharmacies use to make injectable methyl-B₁₂ and not all “raw material suppliers” have equivalent products or purity. The one that Hopewell Pharmacy uses is more expensive and has the highest level of purity available because it comes from PCCA – Professional Compounding Corporation of America – and may be the reason that we get the fewest complaints about the shots being painful or not working as well from those made by Hopewell Pharmacy.]

- F. Injection sites can be varied but it is not dangerous to give the shots in the same location. You may see a "**methyl-B₁₂ tattoo**" as mentioned above. **This is not dangerous and is fairly common.** *However, if you are ever questioned by the school nurse, make sure you let them see my prescriptions along with this entire document with special attention to this comment.*

IV. Injection Technique When Administering The Shots To A Sleeping Child Using Numbing Cream.

Because most parents are hesitant to give their child a shot, this is the method that most parents use, at least for the first few injections. After that, many do not use the numbing cream. Additionally, the shots can be given any time of the day or evening, not necessarily while the child is asleep. Should a child become aware of the event at night, I suggest that the parents give the shots while the child is awake and consider the process no different than what they would need to do to give a shot of insulin. (See Problem 2 farther below)

- a. Methyl-B₁₂ is destroyed by light but is stable at room temperature. Therefore, to avoid the child from feeling a throbbing sensation (not pain) from "cold medicine", put the syringe in a drawer and close it for as long as it takes to bring the syringe to room temperature. Then, just before injecting the medicine, hold the syringe in your hand for a couple of minutes so that it reaches body temperature. Some sensitive children may feel a very slight throbbing sensation as their body detects the change in temperature. Though they feel no pain, they may put their hand over the area where "temperature nerve endings", different from pain nerve endings, have been activated. This causes parents to think that their child has pain when in fact the child's pain nerve endings are quiescent.
- b. Choose any area on the buttocks that has substantial fatty tissue below it. This will not be easy to find for very thin children so just do your best. Because the shots can never go more than just a few millimeters below the skin when injected correctly, you are free to use any area on the buttocks, not just the upper outer quadrant where intramuscular injections are to be given.
- c. Apply enough numbing cream to a wide enough region around your selected target area so that when you return to give the shot approximately 45 minutes later, you will hit the spot without having to have previously marked it. (This is in contrast to what I used to say in earlier versions of this document when I had parents "mark the target area".) The anesthetic cream needs to be in place for approximately 45 minutes to be maximally effective if it is prilocaine/lidocaine, like EMLA. The effect comes on much more quickly, usually within 15 minutes if it is a combination of benzocaine, lidocaine, and tetracaine. The effects of all of them will usually last another hour. However this varies family-to-family so I recommend following the instructions shown above in which I gave parents instructions how to make a chart and use a pin to check the time it takes for their numbing cream to work.
- d. Allow the child to go to sleep.
- e. Do the following in *quick succession*. You may want to *practice* the moves first using an orange or the arm of a sofa that is covered with material (not leather).
 - i. Gently wipe the area with an alcohol swab trying not to awaken your child. **Be sure that the target area and/or the adjacent area have not been soiled with fecal material. Be careful to clean any contaminated areas thoroughly with alcohol.**

[Addendum 2016: most parents thoroughly clean the area before applying the anesthetic cream. Then, as long as their child has not soiled his or her diaper, pull-ups, or underclothes, they give the injection without waking the child from sleep by cleaning the child again with a cool wet alcohol swab. As long as the child's skin is clean and without open sores, this should be fine and nothing to worry about. The reason I say that is because humans introduce far more bacteria into their bloodstream through the "micro-tears" that are made by brushing their teeth or wiping themselves after defecating than they may introduce from the diameter of a BD #328438 needle going through "clean skin".]

- ii. Find your “*target area*”. With your thumb and 3rd finger holding the middle of the syringe (similar to holding a pencil or pen but with different fingers) and your index finger on the plunger of the syringe, *quickly* insert the needle all the way until it automatically comes to a stop at the hub of the needle/syringe. (Think of this move as similar to *tossing a dart, only sideways.*) **THE INJECTION IS TO BE GIVEN AT A VERY SHALLOW ANGLE SO THE MEDICATION IS DELIVERED *JUST UNDER THE SKIN*.** In the past I used to say to inject at a “10 to 30 degree angle”. I have learned that this confused many people because they didn’t know what a 10 degree, 20 degree, or 30 degree angle was. Therefore, forget about the angle because the take home message is to GO SHALLOW, JUST UNDER THE SKIN. This also allows for the injection to go **into the subcutaneous fat** and, because of a “slow-leaching effect”, gives **better results** than if injected into muscle or close to the subcutaneous:intramuscular junction. *[Addendum 2016: see the discussion in “b” in the first section of this document regarding shots being too shallow. At this point in time I recommend no less than a 10 degree angle for the shot.]*
- iii. *Immediately* inject all of the solution within a second or less.
- iv. *Quickly* withdraw the needle and *immediately* put it into the “**sharps container**”. (See “Sharps Container” section below.)
- v. If you do everything gently, your child will usually not awaken. If you do everything quickly and if your child does awaken, you “will be there” to immediately comfort him or her and your child will not know that an injection has occurred.
- vi. Injection sites can be varied but it is not dangerous to give the shots in the same location. You may see a “methyl-B₁₂ tattoo”. This is not dangerous and fairly common.

V. Problem 1: Child That Resists Allowing You To Put On The Local Anesthetic Cream But Does Not Awaken Once She Or He Falls Asleep:

Wait until your child is in a deep sleep. Then apply the anesthetic cream. Wait 30 to 45 minutes and then proceed as above.

VI. Problem 2: If Your Child Is A Light Sleeper And Awakens Whenever You Attempt To Give The Shot At Night, Switch And Give The Shots During The Day:

- I do not recommend alarming a child, scaring a child, or having a child always needing to “guard his butt” from the boogeyman that’s always trying to attack him while he’s attempting to rest in peace!
- Therefore, with these children it is much more important to just teach them that the shot is a part of life, just as a parent must deal with a diabetic child.
- I do not recommend a reward system unless it is absolutely the last straw. The shots are as important as insulin to these children and therefore they need to be administered. Therefore it is a learning experience for both the child and the parents how to do this with the least emotional trauma and the least negotiations possible.
- After the first few shots, the child will learn that the shots do not hurt (if the creams are used) and will therefore be less resistive or not resistive at all.
- Surprisingly it is not uncommon for children to ask for their shots! When children ask for the shots to be given, obviously something good must be happening!

VII. !PAIN?--?PAIN!--!PAIN?

Your child should feel no pain at all for the majority of the shots you administer. The following should be considered whenever you are trying to decide if your child is feeling “movement” by you when you give the shot, a “sensation of fullness”, “a throbbing sensation from temperature changes”, or “true pain”.

- a. Shots should not hurt if the pH is correct. The pH values from compounding pharmacies vary significantly as do other factors that will not be discussed in this document. These pH differences and other variables do cause the shots to range anywhere from being non-painful to painful. Rarely, a bad batch occurs for unknown reasons when all the known variables have remained unchanged.

In my experience, these two factors are the most common causes for painful shots when they occur. After prescribing over 1,000,000 shots and monitoring them personally, I can undeniably state that pain has only been reported on very rare occasions when parents use my supplier. I believe other suppliers can also produce “good shots”. However, in my opinion, there *needs to be some type of standardization between all compounding pharmacies*. This needs to be done in order to guarantee a painless and potent formulation. It needs to become a priority of the compounding pharmacies so all parents can administer methyl-B₁₂ shots without the fear of pain. Unfortunately, though compounding pharmacies can make the solution according to standardized methods, I am not convinced that the effectiveness and the painlessness of the shots are equal among the various suppliers.

- b. *If no local anesthetic was used*, even with perfectly administered shots, at times there may be a set of nerve fibrils that are closer together or more sensitive than others or at times even clumps of nerve fibrils that are present in “knots”. One cannot know ahead of time where these anatomical variations are located. If a child “accidentally” receives a shot in such a location, some discomfort or mild pain may be felt, especially if the local anesthetic cream wasn’t applied properly, long enough, or if left on too long before the shot was given. As a general rule, if the injection site is moved an inch or two, the next shot should be fine.
- c. *If no local anesthetic was used*, the larger the volume of a shot, the more pressure effect or tissue stretching effect that may occur. Therefore, in a sensitive child this may cause a feeling of discomfort. This is one reason to use the strongest shot concentration possible. The one that works the best and lasts the longest comes from a methyl-B₁₂ substrate concentration of 25 mg/mL, not 12.5 mg/mL or even 1 mg/mL. It also important to remember that the sensation of “fullness” may cause a child to “touch the spot” where you administered it but this does not necessarily mean that the child is having a “painful sensation”. This is more likely to happen in bigger children because they require larger shot volumes. Shot volumes of 0.15 mL or more may produce this feeling of fullness and stretching and therefore “may” cause slight pain in a more sensitive child.
- d. If you really think something may be wrong, give yourself a shot to see if it is painful. If it is, either have the pharmacy give you replacement shots from a different batch, or use a different pharmacy. Should you receive a new set of shots from the pharmacy that previously provided the painful shots, ask for an additional shot so you can inject yourself before injecting your child to see if the problem has been corrected.

[Addendum 2016: If you are attempting to determine if “the shots are painful”, you will need to use the anesthetic cream so that you are not mistaking the “pain of the shot similar to a mosquito bite” with a “painful batch of medication”. An alternative to no using the anesthetic cream is to insert the needle through the skin and wait until the “mosquito bite-like pain” has passed before injecting the medication.

In addition, at this point in time I never use other pharmacies than Hopewell Pharmacy because I have had the best clinical results from their “process” of making the injections. Though you may not care, it is still important for me to once again say that I make no income from any medication or supplement that comes from any pharmacy or vendor. Therefore, when I make a

recommendation for you to try a medication or supplement you can be assured that it is not because I am making any income from the medication or supplement.]

VIII. Sharps Container:

It is important to make sure that needles are discarded properly. You can *Google "disposal of insulin syringes"* to get the official recommendation for how to do this. Because the purpose of a sharps container is to protect others from getting stuck by a needle before the needles are properly destroyed, the following description will allow you to make a homemade version of a sharps container that will accomplish this goal.

- a. Obtain a large coffee can that has a plastic lid.
- b. Throw out the coffee if you do not use coffee. If you do, put the coffee in an airtight container.
- c. Wash and dry the container.
- d. Make two slits at a 90-degree angle to each other in the center of the plastic lid.
- e. Securely tape the lid to the can with duct tape.
- f. Check to make sure that you can push a syringe through the slits but that the slits are not wide enough for "little fingers" get through.
- g. When the coffee can is full, securely tape it shut by covering the slits.
- h. Once secured, the can may be disposed with normal trash. It is perfectly legal for "personal" medical waste to be disposed in this manner [in contrast to biohazardous waste generated in a hospital or clinic].